ECONOMIC ANALYSIS OF FINAL EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY

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SECTION ONE

EXECUTIVE SUMMARY

This economic analysis (EA) examines compliance costs and economic impacts resulting from the U.S. Environmental Protection Agency's (EPA's) Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry Point Source Category, hereinafter known as the Final Pharmaceutical Industry Effluent Guidelines. It also investigates the costs and impacts associated with an air rule requiring Maximum Achievable Control Technology (MACT) to control air emissions, both separately and together with the Final Pharmaceutical Industry Effluent Guidelines. The EA estimates the economic effects of compliance with both final rules in terms of total aggregate annualized costs of compliance, facility closures, impacts on firms (likelihood of bankruptcy and effects on profit margins), and impacts on new sources. The EA also investigates secondary impacts on employment and communities, foreign trade, specific demographic groups, and environmental justice. This report includes a Final Regulatory Flexibility Analysis (FRFA) detailing the impacts on small businesses within the pharmaceutical industry to meet the requirements of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). Finally, the EA presents a cost-benefit analysis to meet the requirements of Executive Order 12866 and the Unfunded Mandates Reform Act.

1.1 OVERVIEW

The remainder of this executive summary section follows the general outline of the EA. Section 1.2 summarizes the primary data sources used for the EA, and Section 1.3 briefly profiles the pharmaceutical industry. Section 1.4 presents an overview of the methodologies used in the EA, focusing on the cost annualization model. Section 1.5 presents the facility-level analysis (closure analysis) and the analysis of impacts on new sources. Section 1.6 presents firm-level impacts in terms of likelihood of bankruptcy, while Section 1.7 briefly summarizes employment impacts. Section 1.8 discusses additional secondary impacts on foreign trade, profitability, specific demographic groups, and environmental justice. Section 1.9 summarizes the results of the FRFA, and Section 1.10 presents the results of the cost-benefit analysis.

1.2 DATA SOURCES

The primary data source used in the EA is the survey of the affected subcategories of the pharmaceutical industry. This survey was conducted under the authority of Section 308 of the Clean Water Act and is referred to in this report as the Section 308 Survey. Through this survey, EPA obtained detailed technical and financial information from a sample of pharmaceutical establishments that potentially will be affected by the Final Pharmaceutical Industry Effluent Guidelines. The industry was stratified into the following five groups, based on type of operations conducted: (A) fermentation, (B) biological and natural extraction, (C) chemical synthesis, (D) formulation and mixing/compounding, and (E) research. EPA censused the facilities in most of these categories, for a total of 202 facilities. EPA sampled 42 facilities, representing 84 facilities nationwide, in the following categories: stand-alone facilities in Group D that use solvents and discharge indirectly, and Group D facilities with onsite research facilities (i.e., group D/E) that use solvents and discharge indirectly.

EPA relies on cost data presented in the *Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category* for capital and operating and maintenance (O&M) costs of compliance. For profiling, EPA also relies on data from the U.S. Department of Commerce to supplement Section 308 Survey data. Commerce collects a wide range of data, such as number of establishments, number of employees, volume of shipments, exports, imports, value added, apparent consumption, and manufacturing costs. Other data sources used include those published by the U.S. Food and Drug Administration (FDA), the Bureau of Labor Statistics (BLS), the Pharmaceutical Research and Manufacturers of America (PhRMA), among others, cited where referenced in this report.

1.3 PROFILE OF THE PHARMACEUTICAL INDUSTRY

More than 110,000 pharmaceutical products are currently on the market. These products can be divided into three categories: new drugs (patented, branded drugs); generic drugs (equivalent versions of previously patented drugs), and over-the-counter (OTC) drugs (available without a prescription). Drugs are manufactured using an array of complex batch-type processes and technologies that occur in three main stages: research and development (R&D); fermentation, extraction, and chemical synthesis, which covers the

conversion of organic and chemical substances into bulk active ingredients; and formulation, which refers to the combining of bulk active ingredients with other substances to produce proper dosages.

1.3.1 Facility, Owner Company, and Parent Company Characteristics

According to U.S. Department of Commerce data, 1,343 facilities involved in pharmaceutical production existed in 1990. These facilities employed 194,000 people. Smaller facilities (i.e., those with less than 100 employees) dominate the pharmaceutical industry, although a higher percentage of facilities in the pharmaceutical industry have more than 250 employees than in the manufacturing sector overall. EPA estimates that approximately 286 of the 1,343 pharmaceutical facilities discharge wastewater either directly or indirectly and might be affected by the Final Pharmaceutical Industry Effluent Guidelines. The Section 308 Survey obtained data from 244 of these establishments.

U.S. Department of Commerce data indicate that the value of shipments for the drug industry were $70.0 billion in 1995 ($1990) ($86.2 billion, $1997).[1] In real terms, growth in the industry has averaged 2 to 4 percent annually. The Section 308 Survey data indicate that pharmaceutical facility revenues average approximately $100 million ($123 million, $1997) per facility per year, while average revenues for owner companies are approximately $600 million ($739 million, $1997) per year. The U.S. pharmaceutical industry also has consistently maintained a positive balance of trade, with a trade surplus of $961 million in 1991($1.183 billion, $1997). According to the Section 308 Survey, the mean pharmaceutical export rate for sample facilities was 8.8 percent in 1990.

According to the Section 308 Survey, manufacturing costs for the pharmaceutical industry from 1988 to 1990 rose from $7.4 billion to $9.6 billion ($9.1 billion to $11.8 billion, $1997) at the facility level, from $58.7 billion to $63.8 billion ($72.3 billion to $78.6 billion, $1997) at the owner-company level, and from $149.1 billion to $177.3 billion ($183.6 billion to $218.3 billion, $1997) at the parent company level. In addition, the research and development expenditures for the pharmaceutical industry are more than 16 percent

[1] Costs and benefits in the EA are reported in 1990 dollars. This executive summary reports costs both in 1990 dollars and 1997 dollars. Costs and benefits have been inflated using *Engineering News Record's* construction cost index, March, 1998. Costs and benefits are inflated using the following method: 1997 CCI/1990 CCI = 5,826/4,732 = 1.23119.

of sales, one of the highest proportions for any U.S. industry, while promotional expenditures are approximately 22 percent of the industry's revenues. Overall, the profitability of the industry appears higher than average for U.S. industries as a whole.

1.3.2 Industry Structure and the Pharmaceutical Market

Although the number of pharmaceutical facilities has grown over the last several decades, it is likely that competition would have been greater if high R&D costs, FDA regulations, and other factors did not serve as barriers to entry into the industry. Reflecting these barriers, concentration ratios in some portions of the industry are quite high, although among others, the concentration ratios are lower. Interestingly, exit and entry rates in many drug markets are high. There also is some indication that pharmaceutical companies are vertically integrated. These factors all affect entry of new firms into the pharmaceutical market.

Demand conditions vary significantly among specific drug markets. In the prescription drug market, demand is complicated by the role of health care providers and the presence of health insurance, which reduce the competitive nature of the market. The lack of price sensitivity among consumers, however, is partly offset by increasing sensitivity among insurers. Demand for OTC drugs, on the other hand, conforms more readily to standard models of consumer demand.

The degree of substitutability among pharmaceuticals varies. Patented drugs in the United States enjoy ostensible protection from bioequivalent drugs for a number of years, which can limit direct substitutability. The increase in generic drugs, however, increases substitutability once the patent for a drug expires. For OTC drugs, the market is much like other competitive commodity markets, with a high degree of substitutability causing demand to be relatively sensitive to price changes. In addition, pharmaceuticals are not a very close substitute for most other forms of medical treatments, although they might act as complements.

These factors tend to indicate a relative price inelasticity for pharmaceuticals as a whole. Because regulatory costs associated with the Final Pharmaceutical Industry Effluent Guidelines can affect a large portion of the pharmaceutical industry, the industry as a whole might be able to pass through regulatory costs to consumers in the form of higher drug prices. Individual companies, however, may have less latitude in

passing through costs, although many specific companies do appear to have sufficient market power to pass through regulatory costs. Throughout most of the EA, however, EPA uses the conservative assumption that the affected industry cannot pass through compliance costs to consumers.

1.4 ECONOMIC IMPACT ANALYSIS METHODOLOGY OVERVIEW AND COMPLIANCE COST ANALYSIS

EPA has developed a number of regulatory options, which are analyzed in this EA. These options are divided into those for direct dischargers and those for indirect dischargers. In addition, A and C industry subcategories (representing facilities that use fermentation or biological and chemical synthesis) are distinguished from B and D industry subcategories (representing facilities that use biological and natural extractive processes or that are formulators of pharmaceutical products). Table 1-1 describes these options and provides an option name that corresponds with the option name used in the Development Document and a shortened name that will be used in the EA.

EPA's selected options are as follows:

- A/C Directs: BPT-A/C and BAT-A/C; NSPS-A/C for new sources
- B/D Directs: BPT-B/D and the no-action BAT alternative (not shown in Table 1-1); NSPS no-action alternative (not shown in Table 1-1) for new sources
- A/C Indirects: PSES-A/C; PSNS-A/C for new sources
- B/D Indirects: PSES-B/D; PSNS-B/D for new sources.

Note that the selected NSPS and PSNS options are identical to those selected for existing sources.

Section Four presents the overview of the EA methodology and describes the principal economic and financial models used. Figure 1-1 shows how these principal models (the cost annualization model, the facility closure model, and the owner company model) interact.

The cost annualization model estimates the annual compliance costs to the facility of new pollution control equipment and operations. This model provides the data necessary for the facility- and firm-level

Table 1-1

Summary of Regulatory Options Considered In Economic Analysis[a]

Regulation	Short Option Description for EA Only	Option	Type of Treatment
BPT	BPT-A/C	Revise COD and modify cyanide	Advanced biological treatment
	BPT-B/D	Revise COD and withdraw cyanide	Advanced biological treatment
BAT	BAT-A/C	Add organics, ammonia, and COD and modify cyanide	Advanced biological treatment with nitrification
	BAT-B/D	Add COD and withdraw cyanide	Advanced biological treatment
NSPS	NSPS-A/C	Promulgated level of BPT/BAT control	Advanced biological treatment with nitrification
	NSPS-B/D	Promulgated level of BPT/BAT control	Advanced biological treatment
PSES	PSES-A/C	Add organics, ammonia,and modify cyanide	In-plant steam stripping for organic compounds and ammonia
	PSES-B/D	Add organics and withdraw cyanide	In-plant steam stripping for organic compounds
PSNS	PSNS-A/C	Add organics, ammonia, and modify cyanide	In-plant steam stripping for organic compounds and ammonia
	PSNS-B/D	Add organics and withdraw cyanide	In-plant steam stripping for organic compounds

[a] Many other options were considered and rejected for reasons other than economic achievability. See EPA's Development Document. Also, no-action options are included for all regulations. BCT is not analyzed in the EA. See the Development Document.

Source: U.S. EPA, 1998. *Technical Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*.

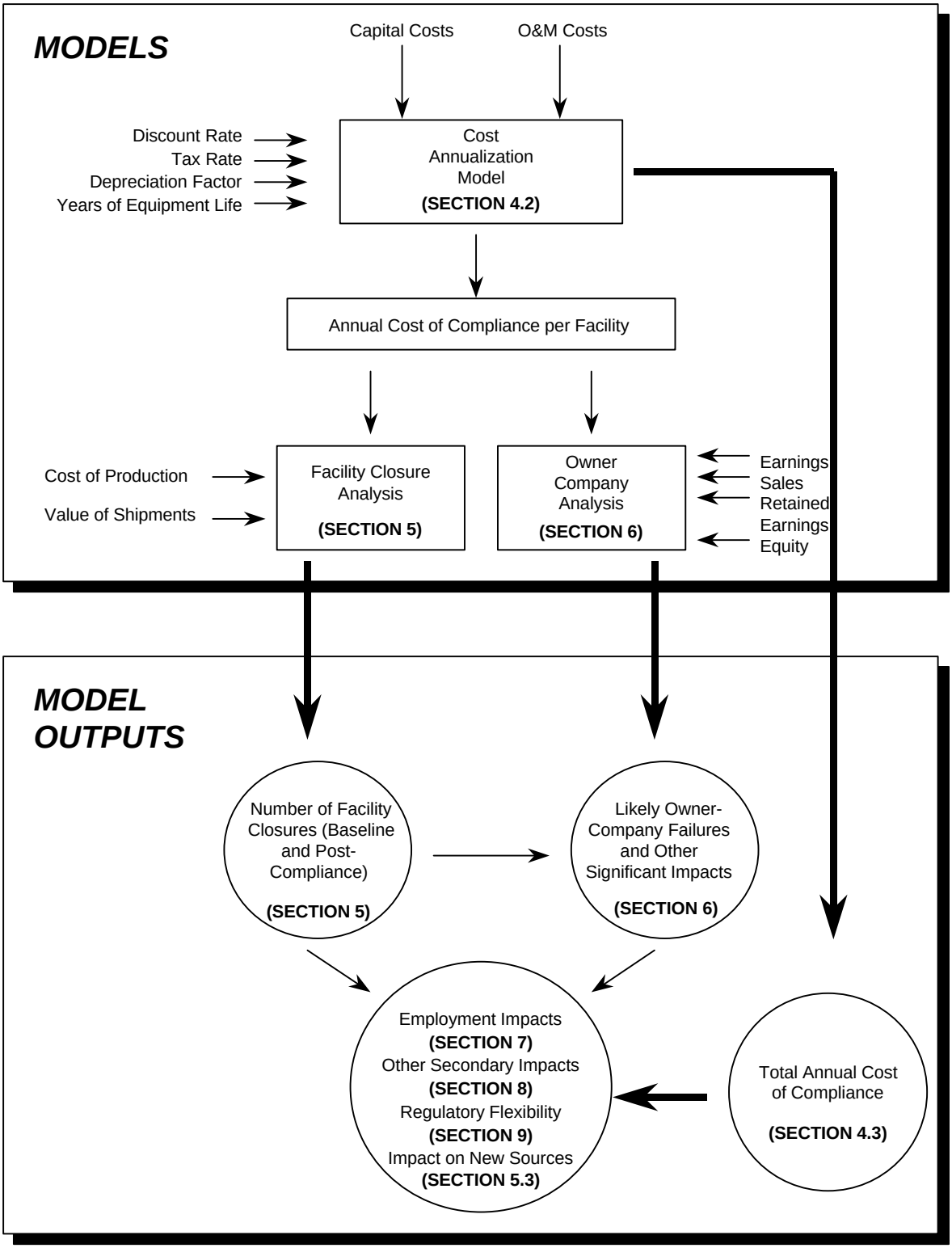

Figure 1-1. Interrelationship of EA methodology components.

analysis. Annualizing costs is a technique that allocates the capital investment over the lifetime of the equipment, incorporates a cost-of-capital factor to address the costs associated with raising or borrowing money for the investment, computes tax-reducing effects of expenditures (e.g., depreciation allowances on corporate income tax), and includes annual O&M costs. The resulting annualized cost represents the average annual payment that a given company will need to make to upgrade its facility.

The annualized costs for each of the selected options for each subcategory are presented in Table 1-2. As the table shows, costs of the options range from $0.2 million to $23.4 million ($1990) ($0.3 million to $28.8 million, $1997), with the selected options ranging from $0.7 million ($0.9 million, $1997) (for B/D directs; cost of BPT only) to $23.4 million ($28.8 million, $1997) for A/C indirects.[2] Each subcategory also has a no-action option. These no-action options are not presented here because they are associated with zero costs. Average costs per facility range from $16,000 to $266,000 ($1990) ($19,000 to $327,000, $1997) among the selected options. Total costs of all selected options is $32.0 million ($1990) ($39.4 million, $1997).

Table 1-3 presents the sum of the selected options, as well as compliance costs for MACT standards requirements (which are annualized using the same cost annualization model and assumptions).[3] As the table shows, the total cost of the selected options for the Final Pharmaceutical Effluent Guidelines is $32.0 million ($1990) ($39.4 million, $1997). With MACT standards wastewater emission control costs included, the water-related cost of the two rules is $37.8 million ($1990) ($46.6 million, $1997). Total cost of both rules together (for facilities in the effluent guidelines analysis only) is $58.3 million ($1990) ($71.8 million, $1997). Total cost of both rules, including MACT standards costs for facilities not covered by the Final Pharmaceutical Industry Effluent Guidelines, is $63.0 million ($1990) ($77.5 million, $1997).

[3] The MACT standards costs are divided into two major components for the purposes of the EA: wastewater emission control costs and total MACT standards costs.

Table 1-2

Annualized Posttax Costs of Compliance with Final Pharmaceutical Industry Effluent Guidelines

Option	Capital Costs		O&M Costs		Annualized Compliance Costs		Facilities Incurring Costs **	Average Costs per Facility ***	
	$1990	$1997	$1990	$1997	$1990	$1997		$1990	$1997
Direct Discharge									
BPT-A/C	$2,422,402	$2,982,437	$1,825,253	$2,247,233	$1,275,930	$1,570,912	24	$53,164	$65,455
BPT-B/D	$1,785,772	$2,198,625	$966,864	$1,190,393	$715,893	$881,400	14	$51,135	$62,957
BAT-A/C	$5,569,135	$6,856,663	$2,423,726	$2,984,067	$1,881,579	$2,316,582	24	$78,399	$96,524
Indirect Discharge									
PSES-A/C	$80,864,749	$99,559,870	$28,597,244	$35,208,641	$23,407,105	$28,818,593	88	$265,990	$327,484
PSES-B/D	$22,067,126	$27,168,825	$5,010,342	$6,168,683	$4,729,914	$5,823,423	153	$30,914	$38,062
All Facilities									
Total Selected Options	$112,709,184	$138,766,420	$38,823,429	$47,799,017	$32,010,421	$39,410,911	279	$114,733	$141,258

* All subcategories have a no-action option; the no-action options are not presented here, since costs for those options are zero.
** The total number of facilities incurring costs includes all facilities except for seven zero discharge facilities.
*** Over number of facilities that incur costs.

Table 1-3

Cost of Selected Options and MACT Standards Costs

Cost Category	Capital Costs		O&M Costs		Annualized Compliance Costs		Facilities Incurring Costs *	Average Costs per Facility **	
	$1990	$1997	$1990	$1997	$1990	$1997		$1990	$1997
Selected effluent guidelines option costs	$112,709,184	$138,766,420	$38,823,429	$47,799,017	$32,010,421	$39,410,911	279	$114,733	$141,258
MACT standards costs (wastewater emission controls)	$30,907,772	$38,053,339	$5,644,605	$6,949,581	$5,810,120	$7,153,362	20	$290,506	$357,668
Total MACT for effluent guidelines analysis	$102,822,547	$126,594,091	$30,535,434	$37,594,921	$26,305,357	$32,386,892	71	$370,498	$456,153
Total MACT standards costs, all facilities	$120,263,588	$148,067,327	$36,007,268	44,331,788	$30,940,806	$38,094,011	NA	NA	NA
Selected effluent guidelines options and MACT standards wastewater costs	$143,616,956	$176,819,760	$44,468,034	$54,748,598	$37,820,541	$46,564,272	279	$135,557	$166,897
Selected effluent guidelines options and MACT standards total costs (effluent guidelines facilities only)	$215,531,731	$265,360,512	$69,358,862	$85,393,938	$58,315,778	$71,797,803	279	$209,017	$257,340
Selected effluent guidelines options and MACT standards total costs (all facilities) ***	$232,972,772	$286,833,747	$74,830,697	$92,130,805	$62,951,227	$77,504,922	NA	NA	NA

* The total number of facilities incurring costs includes all facilities except for seven zero discharge facilities.
** Over facilities that incur costs.
*** Total includes MACT standards costs for some facilities not in the effluent guidelines analysis; the average is calculated only over facilities in the effluent guidelines analysis.

1.5 ANALYSIS OF FACILITY-LEVEL IMPACTS

The facilities in the facility-level analysis are those that are owned by multifacility firms. Impacts on single-facility firms are analyzed in the firm-level analysis to avoid double counting impacts (these firms can be failures only, or failures and closures). Included in this analysis, but not directly analyzed, are 65 facilities (representing 72 facilities nationwide) that certified that the rule would have no impact on the facility. The model places these 72 facilities automatically into the "no closure" category.

Facility closures are determined if the estimated present value of posttax operating earnings of these nonindependent facilities are positive in the baseline analysis but postcompliance are shown to be zero or negative (facilities whose earnings are negative in the baseline are investigated further in the firm-level analysis). The analysis was run for three baseline conditions. In Baseline 1, EPA assumes that the MACT standards costs are not in effect. EPA adjusts Baseline 1 to create Baseline 2 by incorporating the change in posttax earnings associated with the MACT standards wastewater emission control costs. The change in posttax earnings is generated by the cost annualization model. The same procedure is also used to incorporate the change posttax earnings associated with total MACT standards costs to create Baseline 3. Baseline closures are assessed for all three baselines. Costs of compliance with the Final Pharmaceutical Industry Effluent Guidelines are then used to adjust each baseline's earnings to create a postcompliance picture of posttax earnings at the facilities in the facility-level analysis.

Under Baseline 1, 18 facilities out of 206 nonindependent and certifying facilities (8.7 percent) are estimated to close regardless of regulatory requirements (but are investigated further at the firm level). No additional facilities close under Baseline 2 or 3 (thus MACT standards costs by themselves will not have a major impact on the facilities analyzed in this EA).

Postcompliance, under Baselines 1 and 2, no facilities are expected to close as a result of the Final Pharmaceutical Industry Effluent Guidelines. Only in Baseline 3 (with all MACT standards costs considered) does one facility (an A/C indirect discharger) close under the selected options.

For new sources, the selected options are equivalent to the selected options for existing sources. Because the costs for designing pollution control technologies are generally no more expensive than and are usually less expensive than retrofitting pollution control technologies, costs for new facilities will be no more

expensive than costs for existing facilities. Because EPA has shown that the requirements for existing sources are economically achievable, they should be economically achievable for new sources. Furthermore, since the requirements for new sources will not be more expensive than those for existing sources, the rule will not pose a barrier to entry for new sources. Additionally, EPA investigated whether impacts from the effluent guidelines rule (with and without MACT standards costs included) might contribute to firms locating new facilities in foreign countries. EPA determined that the median percentage of the capital costs of compliance (including MACT standards costs) to build a new facility would be negligible (0.21 percent of estimated startup costs at newer surveyed facilities). Thus compliance costs associated with Final Pharmaceutical Industry Effluent Guidelines and/or the MACT standards rule are unlikely to be a major impetus to locating new facilities outside the United States.

1.6 ANALYSIS OF FIRM-LEVEL IMPACTS

EPA investigated the effects of regulatory compliance on owner companies in the firm-level analysis. This analysis uses the Altman's Z equation, which is a multidiscriminant equation that allows a variety of financial ratios to be assessed, weighted by their ability to predict bankruptcy. This equation can be used to predict three outcomes; "bankruptcy likely," "indeterminate," or "bankruptcy unlikely." As in the facility-level analysis, EPA develops three baselines against which to judge the impacts of the Final Pharmaceutical Industry Effluent Guidelines. In each baseline, baseline failures are removed from the analysis, so that the results of the postcompliance analysis show the impacts of the effluent guidelines (and MACT standards costs, where applicable) incremental to firm failures that are estimated to occur regardless of whether the two rules are ever promulgated.

EPA determined that under Baseline 1 (no MACT standards costs considered) 18 firms are likely to fail before the effects of any regulatory costs are considered. These 18 firms are 9.6 percent of the total number of firms in the analysis. One additional firm fails under the assumptions of Baseline 2 (MACT wastewater emission control costs included), and two additional firms fail (compared with Baseline 1) under the assumptions of Baseline 3 (total MACT standards costs included).

Postcompliance compared to Baseline 1, EPA estimates that four firms potentially face bankruptcy (or loss of independent status), or 2.4 percent of all firms. One of these same firms fails under the initial

Baseline 2 assumptions, so does not appear as a postcompliance failure under Baseline 2. Two of these firms fail under the initial Baseline 3 assumptions, so they also do not appear as postcompliance failures under Baseline 3. To be conservative, EPA assumes the four firm failures are attributable to the Final Pharmaceutical Industry Effluent Guidelines, regardless of baseline. Out of the four firm failures projected to occur, only one is expected to result in both a firm failure and a facility closure. The other three firms will incur substantial impacts up to and including firm failure (although in reality they might not fail, but instead might be forced to sell their facilities). Furthermore, all facilities projected to close in the baseline facility closure analysis can be supported by their firms postcompliance without significant impact on these firms.

1.7 NATIONAL AND REGIONAL EMPLOYMENT IMPACTS AND TOTAL OUTPUT LOSSES

This section discusses impacts on national-level and industry-level output and employment from the Final Pharmaceutical Industry Effluent Guidelines (and MACT standards rule). Output is measured in terms of revenues, and under the assumption that industry cannot pass through compliance costs to consumers, the worst-case output loss to the pharmaceutical industry is equal to the pretax costs of compliance. The output losses occurring in the pharmaceutical industry (direct effects) affect input industries, which are industries that provide inputs (e.g., raw chemicals) to the pharmaceutical industry. These effects are known as indirect effects. The direct output losses also affect consumption, as workers lose jobs or work fewer hours and their households reduce purchases of goods and services. These effects are called induced effects. Thus a dollar of output lost in the pharmaceutical industry can also result in additional dollars lost in the U.S. economy as a whole through indirect and induced effects. EPA calculates these additional losses at the national level using input-output multipliers developed by the U.S. Department of Commerce's Bureau of Economic Analysis (BEA).

In addition to output losses, EPA calculates national-level output gains based on output gains in pollution control industries. These industries receive revenues from the pharmaceutical industry for pollution control equipment and operations. Using BEA multipliers, the Agency calculates the subsequent effect of these gains on the pollution control industries' input industries and consumption (i.e., indirect and induced effects). By comparing national-level output losses and gains, EPA develops a *net* national-level output loss or gain.

Because output effects and employment are linked in input-output analysis, EPA calculates employment losses based on output effects using BEA's final demand and direct effect multipliers. EPA uses final demand employment multipliers to compute the total number of jobs lost (including direct, indirect, and induced job losses) given the total loss of output in millions of dollars in the pharmaceutical industry and uses direct effect multipliers to compute the total number of job losses occurring just in the pharmaceutical industry (direct losses), given the total jobs lost nationwide (which include direct, indirect, and induced losses).

EPA also computes employment gains on the basis of output gains in pollution control industries. EPA compares the employment losses and gains to estimate a net gain or loss in employment both at the national level and in the pharmaceutical industry alone (some gains will occur in the pharmaceutical industry since labor to operate pollution control equipment is required).

EPA estimates that at the national level, output gains will exceed output losses. EPA determines a net output gain of about $18.3 million ($1990) ($22.5 million, $1997) as a result of the effluent guidelines. Net output gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total $33.8 million ($1990) ($41.6 million, $1997). EPA also determines that employment gains will exceed employment losses at the national level. The net gain in national-level employment as a result of the effluent guidelines alone will total 218 full-time equivalents (a full-time equivalent, or FTE, equals 2,080 hours per year of labor), and net employment gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total 407 FTEs.

Despite net employment gains at the national level, EPA calculates that losses will exceed gains in the pharmaceutical industry. The direct losses computed on the basis of output losses (and net of gains in employment in the industry due to the need to operate the pollution control equipment) are nearly the same as the closure/failure losses (which are estimated to total 139 FTEs). Output-based losses total 138 FTEs, or 0.1 percent of pharmaceutical employment in the analysis. With MACT standards costs for facilities included in the effluent guidelines analysis, net direct employment losses will total 254 FTEs, or 0.1 percent of employment.

Because output-based employment losses are greater than closure/failure employment losses, nonclosing facilities might experience some small reductions in labor hours and production over time that are additional to the losses of labor hours and production associated with facilities that close or fail (assuming a worst-case scenario where no costs can be passed through to consumers).

The losses in employment due to closures/failures will have a negligible impact on individual communities. No community is expected to experience a change in its unemployment rate exceeding 0.4 percent.

1.8 OTHER SECONDARY IMPACTS

In this section of the report, EPA investigates five separate types of impacts: impacts on trade (including impacts on profitability that might encourage firms to relocate themselves or facilities to foreign countries), impacts on inflation, impacts on POTWs through reductions in revenues related to reductions in loadings, particularly in biological oxygen demand (BOD), impacts on distributional equity through potential product price increases, and impacts on environmental justice (comparing who ultimately pays for a regulation compared to who ultimately benefits from it).

To investigate trade impacts, EPA determined the foreign shipments of closing facilities (determined in the facility-level analysis), under the assumption that lost production might be supplied by foreign sources. The facilities estimated to close, however, do not have any foreign shipments, thus their closing will have no impact on the balance of payments.

EPA then investigated impacts of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule on profit margins (measured as posttax EBIT divided by revenues). Only eight firms (nine firms if MACT standards costs are considered as well) are expected to experience significant changes in profit margins and these firms are considered the least likely to relocate their facilities to foreign countries. These firms tend to be small, and, generally, they are unlikely to have experience in international locations. The transaction costs of learning how to operate in foreign countries, along with the expense of relocating, are likely to be prohibitively expensive for these firms. Thus EPA has determined that even under the combined

effect of the two rules, firms are unlikely to relocate to foreign countries to escape the impacts on profitability induced by the two rules.

The rules, together or separately, will have no major impact on inflation, as the costs of the two rules are at most only 0.001 percent of gross domestic product (GDP).

EPA also expects that impacts on POTWs will be minimal. The Agency expects that the reduction in the BOD discharged to POTWs as the result of compliance with PSES for these pollutants will be minimal. As a result, EPA believes that any reduction in revenue to POTWs that charge industrial users subject to the PSES will be insignificant. Even if BOD loads to POTWs were to drop substantially, there are a number of mitigating factors to consider. First, EPA estimates that very few POTWs receive a large portion of their flow from pharmaceutical facilities. Second, the way in which POTWs set their fees must be considered. Many POTWs price their services on the basis of total flow alone, and others on the basis of total flow but only secondarily on loads or concentrations. A drop in the load to a POTW thus might not trigger any reduction in revenues. Third, even if a POTW receives a large portion of flow from affected pharmaceutical facilities, and it sets fees on the basis of pollutant loadings or concentrations rather than raw volume, effects on both revenues and costs must be considered. With smaller loads or lower concentrations of pollutants, POTWs' costs can also be reduced. Finally if any revenue shortfall were to occur, POTWs might raise rates very slightly and thus cost increases would be spread out over a large number of users, further diluting any impacts.

The Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule, together or separately, will have no major distributional impacts. Compliance costs are generally a very small percentage of baseline pharmaceutical operating costs, thus any cost increases are likely to be very small and are not likely to have any major effect on any one group of consumers. EPA did investigate the products at several firms where, if 100 percent of compliance costs were passed through to consumers, a significant price increase might occur (a total of 9 firms showed the potential for price increases of 10 percent or more on their products). These products might tend to be used more by several groups of consumers that in some cases are also more sensitive to price increases (since some groups are more likely to be uninsured). The potentially disproportionate users include children, young adult women, and the elderly. However, given the limited number of products involved (40 out of more than 110,000 pharmaceutical products), EPA expects that impacts on distributional equity will be minimal.

Impacts on environmental justice also should be minimal. As noted above, any price increases on drugs will be very small and impacts on disadvantaged groups such as the poor and certain minority groups will be minimal. Furthermore, many of these groups will benefit from the effluent guidelines final rule. A large portion of the affected facilities are located in urban areas where poor or minority populations tend to be high. Although everyone benefits, it is these populations that will likely benefit the most from the cleaner water resulting from both rules.

1.9 FINAL REGULATORY FLEXIBILITY ANALYSIS

EPA estimates that a maximum of 145 out of 190 (76 percent) pharmaceutical firms subject to the rule might be classified as small under SBA definitions. Small firms are defined in 13CFR Part 121 either by their employment size or by their revenues. The relevant portion of the pharmaceutical industry is defined as small using an employment size of either 500 or 750, depending on the 4-digit SIC designation. For simplicity, and as done in the Initial Regulatory Flexibility Analysis (IRFA) at proposal, this FRFA designates all pharmaceutical firms as small if they employ fewer than 750 persons.

EPA undertook an initial analysis as suggested by SBREFA guidance issued by the Agency. This initial analysis, the revenue test, determines how many and the percentage of small firms whose compliance costs are more than 1 percent and more than 3 percent of revenues. If the number or percentage of firms exceeding these benchmarks is low (for example, if fewer than 100 firms incur costs that are greater than 1 percent of annual revenues and if fewer than 100 firms incur costs that exceed 3 percent of annual revenues), the rule is considered to meet qualifications allowing the EPA Administrator to certify the rule as having no significant impact on a substantial number of small entities. In the case of the Final Pharmaceutical Effluent Guidelines, EPA determined that only 4 small firms or 3.2 percent of all small firms that could be analyzed will incur annual compliance costs that are greater than 1 percent of annual revenues and no firms will incur costs exceeding 3 percent of annual revenues. Even when MACT Baseline 3 costs are added in, only 6 firms (4.8 percent) will incur annual compliance costs that are greater than 1 percent of revenues and 1 firm (0.8 percent) will incur annual costs greater than 3 percent. The Final Pharmaceutical Industry Effluent Guidelines are thus considered a Category 1 rule. Category 1 rules may be certified as having no significant impact on a substantial number of small entities without performing a FRFA. To further support this finding, however, EPA follows with a FRFA.

EPA has selected facility closures and firm failures as identifying measures of significant impact in this FRFA. One facility owned by a multifacility firm will close (although only if MACT standards costs are included), one single-facility firm will fail and close, two single-facility firms will fail but will probably not close (i.e., they will lose their financial independence), and one multifacility firm will fail or must sell (but not close) one or more of its facilities. All of the firms associated with these impacts are small firms. Given that 76 percent of all affected firms are small, this result is not disproportionate. If exact proportionality of impacts were to have occurred, we could expect out of five significantly affected firms that four would have been small. The difference between four significantly affected small firms out of five total affected firms (large or small) and five significantly affected small firms out of five total affected firms is minimal.

1.10 COSTS AND BENEFITS OF THE FINAL PHARMACEUTICAL INDUSTRY EFFLUENT GUIDELINES AND THE MACT STANDARDS RULE

EPA has undertaken this analysis to address the requirements of Executive Order 12866 and the Unfunded Mandates Reform Act. Agencies are required to address the costs and benefits of a regulation under both of these if the annual cost of a rule on either private industry or governments is expected to be $100 million or more. Although each rule independently will not be close to $100 million in annual costs, the combined costs of the two rules is greater than $100 million when all social costs are considered and when costs are inflated to current-year dollars.

1.10.1 Social Costs

The costs of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are presented in Section 1.4 of this executive summary. These costs, however, are only the costs to industry. The tax savings realized by industry are, in fact, still costs borne by the state and federal governments as forgone income. Thus the total social cost (costs to all segments of the economy) is understated by the amount of these tax shields. Other costs not included in the preceding estimate are costs to administer the regulations (permitting costs) and costs associated with unemployment (administration costs only; unemployment benefits are transfers, and willingness to pay to avoid unemployment are assumed captured in the compliance

costs of facilities that are projected to close postcompliance). These costs, along with the pretax annual costs of compliance are the major components of social costs.

EPA estimates the pretax costs of compliance using the same cost annualization model used to estimate posttax costs of compliance with Final Pharmaceutical Industry Effluent Guidelines. The model outputs both sets of costs. Table 1-4 presents the pretax costs of compliance for the Final Pharmaceutical Effluent Guidelines and the MACT standards rule (as computed by OAQPS), separately and together. As the table shows, the social (pretax) cost of compliance for the subcategories under the effluent guidelines range from $1.1 million to $36.1 million annually ($1990) ($1.4 million to $44.5 million, $1997), depending on subcategory. The selected options have an annualized pretax cost of $49.4 million ($1990) ($60.8 million, $1997).

EPA assumes that all direct dischargers are currently covered by a permit and these facilities will not be associated with incremental costs to permit. Indirect dischargers are assumed to require incremental effort to permit.

EPA estimates that the average annualized cost of $206,585 ($1990) ($254,345, $1997) is the social cost of administering the rule. Even with the conservative assumptions used in the analysis (i.e., that all permitting costs are incremental to current costs of administering indirect dischargers, even though most have some level of permits in place, and that permits will be costlier mass-based not concentration-based permits), administrative costs are less than 1 percent of the estimated compliance costs.

Finally, EPA estimates the costs of administering unemployment, based on an estimated $100 per laid-off worker and the projected national-level impacts on employment, including indirect and induced employment effects (which overstates actual employment losses, because these estimates are hours lost, not necessarily jobs lost). EPA estimates that maximum unemployment benefits administration costs will be $10,730 ($13,210, $1997) annually over all selected options.

Table 1-4 also presents the total social costs associated with each of the selected options. These costs range from $1.1 million to $36.2 million annually ($1990) ($1.4 million to $44.6 million, $1997), depending on the subcategory. The selected options are associated with annual total social costs of $49.6 million ($61.0 million, $1997).

Table 1-4

Social Costs of Compliance
(thousands of dollars)

Regulatory Option	Compliance Costs		Administrative Costs		Unemployment Benefits Administration Costs		Total Costs	
	$1990	**$1997**	**$1990**	**$1997**	**$1990**	**$1997**	**$1990**	**$1997**
BAT-A/C (with BPT)	$4,942.59	$6,085.26	$0.00	$0.00	$1.07	$1.32	$4,943.66	$6,086.59
BPT-B/D only	$1,121.23	$1,380.45	$0.00	$0.00	$0.24	$0.30	$1,121.48	$1,380.75
PSES-A/C	$36,131.97	$44,485.32	$76.02	$93.59	$7.86	$9.67	$36,215.84	$44,588.58
PSES-B/D	$7,166.66	$8,823.52	$130.57	$160.75	$1.56	$1.92	$7,298.78	$8,986.19
Total Selected Options	$49,362.44	$60,774.54	$206.59	$254.35	$10.73	$13.21	$49,579.76	$61,042.10
Total MACT, efluent guidelines facilities	$40,325.06	$49,647.81	NA *	NA *	$8.77	$10.80	$40,333.83	$49,658.60
Total MACT, all facilities	$47,446.95	$58,416.21	NA *	NA *	$10.32	$12.71	$47,457.27	$58,428.92
Total MACT, effluent guidelines + Selected Options	$89,687.50	$110,422.35	$206.59	$254.35	$19.50	$24.01	$89,913.59	$110,700.71
Total MACT, all facilities + Selected Options	$96,809.39	$119,190.76	$206.59	$254.35	$21.06	$25.92	$97,037.03	$119,471.03

* Administrative costs were not calculated for MACT but are expected to be small relative to the total costs of the two rules combined. Unemployment benefits administration costs were calculated using net FTE loss from Table 7-9.

1.10.2 Pollutant Reductions

The selected options are associated with postcompliance removals of 16.2 million pounds and 373,198 pound equivalents (pounds weighted by toxicity) from waters of the U.S. Note that these removals do not include the air removals associated with the MACT standards rule. These removals amount to an additional 48 million pounds.

1.10.3 Benefits of the Final Pharmaceutical Industry Effluent Guidelines

The benefit categories considered in this assessment of the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are identified below. Specifically, this assessment addresses the following:

- Human health and agricultural benefits due to reductions in emissions to air of ozone precursors (i.e., reductions in volatile organic compounds [VOC] emissions)
- Human health benefits due to reductions in excess cancer risk
- Ecological and recreational benefits (environmental) due to improved water quality, including intrinsic benefits
- Benefits from reductions in interference and passthrough problems, improvements in worker health, and reductions in analytical costs at POTWs
- Human health benefits due to reductions in systemic and other risks, such as risk of developmental effects or individual organ toxicity

For the first three benefit categories, sufficient information is available to monetize the benefits of the final rules. The dollar magnitude of the benefits for the other two benefit categories cannot be quantified. The methodology and data used in the estimate of all benefits, as well as the limitations, are described in detail in EPA's *Environmental Assessment of the Final Industry Guidelines for the Pharmaceutical Manufacturing Industry* (1998).

As shown in Table 1-5, the estimated annual monetized benefits resulting from the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT

Table 1-5

Total Costs and Benefits of the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule
(thousands of dollars)

	Total Social Cost or Benefit Effluent Guidelines		Total Social Cost or Benefit MACT Standards Rule		Total Social Cost or Benefit Effluent Guidelines + MACT Standards Rule	
Type of Benefit	**$1990**	**$1997**	**$1990**	**$1997**	**$1990**	**$1997**
Compliance Costs	$49,362	$60,775	$47,447	$58,416	$96,809	$119,191
Administrative Costs	$207	$254	unquantified *	unquantified	$207	$254
Unemployment Administrative Costs	$11	$13	$10	$13	$21	$26
Total Social Costs	$49,580	$61,042	$47,457	$58,429	$97,037	$119,471
Human Health Benefits **	$123 - $9,040	$151 - $11,130	$3,150 - $54,600	$3,878- $67,223	$3,273 - $63,640	$4,030 - $78,353
Recreational Benefits	$419 - $1,495	$516 - $1,841	unquantified	unquantified	$419 - $1,495	$516 - $1,841
Nonuse Benefits	$210 - $748	$259 - $921	unquantified	unquantified	$210 - $748	$259 - $921
POTW Benefits +	unquantified	unquantified	unquantified	unquantified	unquantified	unquantified
Total Benefits ++	**$752 - $11,300**	**$926 - $13,912**	**$3,150 - $54,600**	**$3,878 - $67,223**	**$3,902 - $65,900**	**$4,804 - $81,135**

* Administrative costs were not calculated for the MACT standards rule but are expected to be small relative to the total costs of the two rules combined.
** Includes ozone reductions and cancer reductions.
+ Data are not available to monetize this benefit.
++ This range includes $285,000 to $1.0 million ($1990) ($340,000 to $1.2 million, $1997) of the environmental benefits that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions portion of the MACT standards rule. The total benefits numbers differ slightly from those presented in the preamble due to rounding of the benefits to two significant digits in the preamble.

standards rule will range from $0.7 million to $11.3 million ($1990) ($0.9 million to $13.9 million, $1997). This range includes $285,000 to $1.0 million ($340,000 to $1.2 million, $1997) of the environmental benefits that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT standards rule. The annual monetized benefits resulting solely from the MACT standards rule are estimated to range from $3.2 million to $54.6 million ($1990) ($3.9 milion to $66.9 million, $1997), for a total over both rules of $3.9 million to $65.9 million ($1990) ($4.8 million to $80.8 million, $1997) annually. The largest benefit category is human health benefits, with about 90 percent of the total dollar value of benefits under the combined rules. Table 1-5 summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of the final rules and in placing a dollar value on these effects. These monetized benefits ranges do not reflect many of the benefit categories expected to result under the final rules, including reduced systemic human health hazards; improved POTW operations/conditions; and improved worker health at POTWs. Therefore, the reported benefit estimate understates the total benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Table 1-5 also presents the social costs of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule. Only the costs and benefits of the selected effluent guidelines options are presented here.

As the table shows, the Final Pharmaceutical Industry Effluent Guidelines are associated with costs totaling $49.6 million ($61.0 million, $1997), with benefits totaling $0.7 million to $11.3 million ($1990) ($0.9 million to $13.9 million, $1997). With costs and benefits of the MACT standards rule included, costs of both rules are $102.2 million ($1990) ($125.8 million, $1997) and benefits of both rules range from $3.9 million to $65.9 million ($1990) ($4.8 million to $81.1 million, $1997).

SECTION TWO

DATA SOURCES

This EA relies on a variety of data sources, including the Section 308 Pharmaceutical Survey conducted specifically for this regulatory development effort, the U.S. Department of Commerce, the U.S. Food and Drug Administration (FDA), Bureau of Labor Statistics (BLS), Dun & Bradstreet (D&B), Robert Morris Associates (RMA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and various journal articles. Most of the analyses conducted in Sections Four through Ten make extensive use of the data collected from the Section 308 Pharmaceutical Survey. Other data sources were used primarily in the development of the industry profile in Section Three. Data gathered in the profile, however, provide the foundation for much of the analysis in later sections.

The following sections describe the three principal data sources for this EA: the Section 308 Pharmaceutical Survey, sources available through the U.S. Department of Commerce, and data on compliance costs of an air rule requiring Maximum Achievable Control Technology (MACT) to control air emissions. This MACT standards rule also will affect many of the same facilities and will be finalized at nearly the same time as the Final Pharmaceutical Industry Effluent Guidelines. Other data sources are described, as necessary, in Sections Three through Ten.

2.1 THE SECTION 308 PHARMACEUTICAL SURVEY

The Section 308 Pharmaceutical Survey obtained detailed technical and financial information from a sample of pharmaceutical establishments potentially affected by EPA's proposed effluent guidelines. EPA stratified the industry into five groups based on type of operation:

- A) Fermentation
- B) Biological and natural extraction
- C) Chemical synthesis

- D) Formulation and mixing/compounding
- E) Research

The stratification permitted EPA to census (i.e., survey all facilities) facilities within some subcategories and sample facilities within others. EPA took a census of all facilities that (1) manufacture active ingredients (subcategories A, B, C) and directly discharge process wastewater and (2) perform formulating and mixing/compounding (subcategory D) and directly discharge or directly and indirectly discharge process wastewater. EPA judged that a census of these facilities was necessary to achieve statistical accuracy because the overall universe was small, few facilities were in the same combination of subcategories, and each facility was expected to have wastewater generated by proprietary processes that would make their effluent significantly different from other facilities in the same subcategory. Overall, EPA conducted a census of 202 facilities in these four subcategories.[1]

EPA also censused subcategory D stand-alone facilities that use solvents and discharge indirectly, and subcategory D facilities with onsite research facilities (i.e., subcategory D/E) that use solvents, discharge indirectly, and have fewer than 19 employees or more than 747 employees. For subcategory D indirect discharging facilities with between 19 and 168 employees and between 169 and 747 employees, EPA used a sampling methodology. The sampling methodology stratified these facilities by flow rates and employee size using a linear regression between the log of the number of employees and log of the flow rate. Employee and flow rate data were available from EPA's *Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category*.[2] Overall, EPA sampled 42 pharmaceutical facilities in subcategories D and D/E.[3] Survey results used throughout the EA are weighted according to the sampling plan. Subcategory D and D/E facilities with between 19 and 747 employees received a weight of approximately 2 (because only about half of these facilities were surveyed). (All subcategory D facilities are grouped with subcategory B facilities for the purpose of this analysis, which is discussed in Section Four.) All

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[1] U.S. EPA, 1990. U.S. Environmental Protection Agency. *Supporting Statement for OMB Review: Detailed Questionnaire for the Pharmaceutical Manufacturing Industry*. Washington, DC: Office of Water Regulations and Standards.

[2] U.S. EPA, 1983. U.S. Environmental Protection Agency. *Development Document for Effluent Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category*. Washington, DC: U.S. EPA.

[3] U.S. EPA, 1990. *Op. cit.*

other facilities received a weight of 1. The coefficient of variation in any particular strata (i.e., combination of subcategory and flow group) is not greater than 15 percent. Thus the total survey universe comprises 286 facilities, 202 of which were censused and 84 of which were sampled at approximately a 50 percent sampling rate.

EPA determined that no information was needed from three groups of pharmaceutical facilities:

- Facilities that do not discharge wastewater
- Facilities that do not use solvents and whose only source of process wastewater is from formulation and mixing/compounding
- Stand-alone research facilities

These facilities do not require effluent guidelines because their impact on water quality and POTW operations is considered to be negligible.

The survey data were used extensively in the development of BPT, BCT, BAT, NSPS, PSES, and PSNS regulations for the industry. Surveyed facilities provided technical information on pharmaceutical products; compound and chemical usage and disposition; waste minimization and pollution prevention activities; wastewater generation, collection, and conservation; wastewater treatment; steam stripping; and wastewater characteristics. The survey also collected financial data such as number of employees; ownership structure; discount rate; market value of land, buildings, and equipment; value of shipments; manufacturing costs; assets; liabilities; earnings; and net income. Financial data were collected at the facility, owner-company, and parent company levels.

All surveyed facilities were given the option to legally certify that the facility would incur no significant economic impact as a result of the effluent guidelines. These facilities gave up their right to challenge aspects of the Final Pharmaceutical Industry Effluent Guidelines based on economic achievability so long as the cost of compliance with the effluent guidelines ultimately promulgated by EPA does not exceed the compliance cost estimated in the survey. Certifying facilities were excused from completing the bulk of the financial questionnaire. Sixty-five of the 244 surveyed facilities certified no significant economic impact and thus did not provide financial data.

2.2. U.S. DEPARTMENT OF COMMERCE SUPPLEMENTAL DATA

The EA supplements financial data collected in the Section 308 Pharmaceutical Survey with data from the U.S. Department of Commerce. Commerce divides the pharmaceutical industry into four 4-digit Standard Industrial Classifications (SICs):

- ***SIC 2833 Medicinal and Botanical***. Establishment primarily engaged in: (1) manufacturing bulk organic and inorganic medicinal chemicals and their derivatives and (2) processing bulk botanical drugs and herbs.

- ***SIC 2834 Pharmaceutical Preparations***. Establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. The greater part of the products of these establishments are finished in the form intended for final consumption, such as tablets, capsules, liquids, etc. These pharmaceutical preparations are promoted to the medical profession (prescription drugs) and the general public (over-the-counter [OTC]).

- ***SIC 2835 In Vitro and In Vivo Diagnostic Substances***. Establishments engaged in the manufacturing of chemical, biological, and radioactive substances used in diagnosing or monitoring human and animal health by identifying and measuring normal and abnormal constituents of body fluids or tissues.

- ***SIC 2836 Biological Products, Except Diagnostic Substances***. Establishments engaged primarily in the production of bacterial and virus vaccines, toxoid, and analogous products, serums, plasmas, and other blood derivatives for human and veterinary use.

Commerce collects a wide range of data at the 4-digit SIC level including number of establishments, number of employees, volume of shipments, exports, imports, value added, apparent consumption, manufacturing costs, and other data. Commerce further segments the pharmaceutical industry into 14 five-digit and hundreds of seven-digit SIC codes. Comprehensive financial data at the five- and seven-digit levels, however, is available only under SIC 2834 Pharmaceutical Preparations. Commerce data are reported in publications such as the *Census of Manufactures*, *County Business Patterns*, and *U.S. Industrial Outlook*. The EA uses the most current available data from these sources in the development of the industry profile in Section Three.

Numerous other data sources employed by EPA in the EA are organized by SIC code. For example, price indices generated by BLS and financial ratio data reported by D&B and RMA are organized by SIC code.

A major difficulty with using data organized by SIC is its inability to capture all establishments engaged in the production of pharmaceuticals. Commerce classifies facilities by their primary line of business. Thus, only establishments that garner at least 50 percent of their revenues from pharmaceutical-related business are classified in the four pharmaceutical SIC codes. Facilities that manufacture pharmaceuticals but list some other line of business (e.g., chemical production) as their primary SIC are not captured in the four pharmaceutical SICs. Thus, Commerce data do not provide a complete picture of the U.S. pharmaceutical industry.

The Section 308 Pharmaceutical Survey data cover only a subset of the pharmaceutical industry. The five categories used to segment the pharmaceutical industry in the survey do not correspond with the four pharmaceutical SICs. Moreover, surveyed facilities were not asked to report their SIC. Thus, no direct comparison can be made between Commerce and survey data.

2.3 MACT STANDARDS COST DATA

EPA's Office of Water, Engineering and Analysis Division, received cost data from EPA's Office of Air Quality Planning and Standards (OAQPS). These data included capital and operating costs for 98 facilities to install and operate equipment to meet MACT air quality standards. Of these 98 facilities, 71 will incur both MACT standards and effluent guidelines costs. Because the two rules (effluent guidelines and MACT standards) will be finalized in 1998, EPA considers the effect of MACT standards costs on these 71 facilities in this EA. MACT standards costs include costs for six components: equipment leaks, dedicated process vents, nondedicated process vents, storage tanks, partially soluble wastewater, and soluble wastewater. The last two MACT standards cost components are considered wastewater emission control costs; and the entire group of costs are considered total MACT standards costs. EPA has developed three baselines for assessing impacts of the Final Pharmaceutical Industry Effluent Guidelines. Baseline 1 uses just the Section 308 Pharmaceutical Survey data to establish current conditions. EPA incorporates the wastewater emission cost portion of the MACT standards costs into Baseline 1 to create a Baseline 2, and incorporates total MACT standards costs into Baseline 1 to create Baseline 3 (see Sections Five and Six for more details). The impacts of the Final Pharmaceutical Industry Effluent Guidelines are judged against all three baselines. Appendix B presents the costs as received from OAQPS and used in creating Baselines 2 and 3.

SECTION THREE

PROFILE OF THE PHARMACEUTICAL INDUSTRY

This profile of the U.S. pharmaceutical industry provides descriptive and statistical information necessary for developing the EA methodology presented in Section Four and for interpreting its results. This section is organized into three subsections that address the principal determinants of supply and demand for U.S. pharmaceuticals and present key industry statistics. The section begins with an introduction to the pharmaceutical industry—its functions, products, regulatory environment, and manufacturing processes. Section 3.2 presents basic facility, owner company, and parent-level statistics including number of facilities, employment, value of shipments, international trade, production costs, and baseline financial conditions. Finally, Section 3.3 discusses market structure and demand in the pharmaceutical industry. Key topics such as barriers to entry, vertical integration, industry concentration, and the price elasticity of pharmaceutical demand are covered. The section concludes with an analysis of the industry's ability to raise prices in response to increased regulatory costs.

3.1 STRUCTURE OF THE PHARMACEUTICAL INDUSTRY

Any EA requires an understanding of the basic structure of the affected industry so that impacts on specific members, functions, or processes can be identified, distinguished, and estimated. At its core, the pharmaceutical industry is the collection of commercial enterprises engaged in the discovery, manufacture, and sale of drugs. As such, the industry plays a central role in public health—it produces the steady stream of medicines needed to prevent, diagnose, and treat disease; to extend life and improve our quality of life; and to continually advance the quality, breadth, and effectiveness of available health care. Producing this steady stream of medicines involves a range of activities:

- Research and development (R&D)—to discover, enhance, and devise reliable manufacturing processes for drugs.
- Bulk manufacturing—to produce large volumes of drug ingredients.

- Finished dosage form manufacturing—to combine drug ingredients in a form suitable for sale and use.

- Marketing—to promote and sell drugs (e.g., by informing health care providers and consumers of their availability, features, and proper use).

Individual companies in the pharmaceutical industry may specialize in any one or more of these activities. In addition, they may specialize in researching, manufacturing, and/or marketing any one or more of the major types of drugs—new prescription drugs, generic prescription drugs, and over-the-counter (OTC) drugs—or in any one or more therapeutic area. Indeed, pharmaceutical companies are a diverse lot, including companies that focus on just one function (e.g., bulk manufacturing) for one product group (e.g., OTCs), companies that combine a couple of or a few functions for more than one product group, and companies that perform all functions for all types of products. In general, smaller pharmaceutical companies tend to specialize in the manufacture or sale of bulk ingredients or generic products, or in the development of one or a few very specific products (e.g., bioengineered anticancer drugs). Many large pharmaceutical companies, on the other hand, are "innovative" companies (i.e., that discover, produce, and/or market new drugs) that also produce generic and OTC drugs.

Although most people think of drugs as chemicals used to treat human disease, these products encompass a broad range of substances, including synthetic/semisynthetic chemical, biological, recombinant DNA (bioengineered), and radioactive products; drugs for human and veterinary use; and therapeutic drugs (used to prevent, ameliorate the symptoms of, or treat disease) and diagnostic substances (used to diagnose disease or monitor health status). Thus, this analysis encompasses all these types of products. For the purpose of this EA, biological products, veterinary products, and diagnostic products are considered subsets of new and generic drugs.

The pharmaceutical industry is regulated by a variety of state and federal agencies that play a major role in nearly all pharmaceutical activities. At the core of pharmaceutical regulation is FDA, which is charged with ensuring the safety and effectiveness of drugs intended for human and animal use. To this end, FDA reviews drugs before they reach the market, monitors clinical trials, dictates labeling requirements, specifies acceptable manufacturing practices, and conducts postmarket surveillance. Other federal and state agencies, such as the Occupational Safety and Health Administration (OSHA) and EPA, regulate the health, safety, and environmental practices of the pharmaceutical industry. Federal and state governments also exert

considerable influence on the industry by serving as major third-party payers of prescription drugs under Medicare and Medicaid programs (see Section 3.3.2), purchasing large quantities of pharmaceutical products through the U.S. Public Health Service and the Veterans Administration (VA), sponsoring pharmaceutical R&D through the National Institutes of Health (NIH), and crafting tax policies that can influence product development.

The central goal of this government oversight and influence is to achieve socially desirable ends (e.g., product safety, a clean environment, etc.) without excessively compromising the industry's ability to discover, produce, and sell drugs needed to serve the nation's public health interest. To assess potential impacts of EPA's proposed effluent limitations guidelines and standards on individual components of the pharmaceutical industry and the industry as a whole, this EA will segment the pharmaceutical industry by:

- U.S. Department of Commerce SIC code (SICs 2833, 2834, 2835, and 2836).
- Major type(s) of drugs produced.
- Principal manufacturing processes.

Sections 3.1.1, 3.1.2, and 3.1.3 describe these three segmentation schemes in more detail.

3.1.1 Department of Commerce SIC Codes

As noted in Section Two, U.S. Department of Commerce divides the pharmaceutical industry into four 4-digit SIC codes:

- SIC 2833 Medicinal and Botanical
- SIC 2834 Pharmaceutical Preparations
- SIC 2835 In Vitro and In Vivo Diagnostic Substances
- SIC 2836 Biological Products, Except Diagnostic Substances

This segmentation scheme is mainly useful in interpreting Commerce data on pharmaceutical establishments, employment, production, consumption, and the like. These data are presented and discussed throughout the remainder of this document.

3.1.2 Major Types of Drugs Produced

Currently, the pharmaceutical industry produces more than 110,000 pharmaceutical products.[1] Most commonly, these products are classified as new (patented, branded) drugs, generic drugs, or OTC drugs. FDA defines these product types as follows:

- A new drug is an entirely new molecular entity (NME); a new ester, salt, or other noncovalent derivative; a new formulation; for a new indication; or a new combination (see Figure 3-1).
- Generic drugs are equivalent versions of previously marketed, patented drugs and generally appear on the market several years after patent expiration.
- OTC drugs are available without a prescription and generally undergo a less rigorous review process than do prescription drugs. Examples of OTC drugs include aspirin, cough medicines, and home pregnancy tests.

As can be seen in Figure 3-2, new drugs accounted for the majority (62.3 percent by total dollar volume) of industry sales in 1991. OTC drugs accounted for 27.5 percent of sales and generic drugs made up the remaining 10.2 percent. More recent independent data were not available, but many industry analysts have observed a steady increase in the generic and OTC shares of the total pharmaceutical market. Most attribute this trend to cost pressures (encouraging greater use of generics) and numerous conversions of prescription drugs to OTC products. It should be noted, too, that because prescription pharmaceuticals are considerably more expensive than generic and OTC products, dollar sales volume figures for these product groups do not match the frequency of their usage. By unit sales or number of prescriptions filled, generic drugs are more dominant than their dollar sales suggest. In 1991, for example, generic drugs accounted for 34 percent of all prescriptions filled, but only 19.1 percent of total prescription drug sales, and just 12.6 percent

[1] As cited in Research Triangle Institute (RTI), 1993. *Economic Analysis of Effluent Guidelines Regulations for the Pharmaceutical Industry.* Draft Report. Contract No. 68-C8-0084. Research Triangle Park, NC: RTI.

New molecular entity (NME). A drug for which the active moiety (either as the unmodified base compound or an ester, salt, clathrate, or other noncovalent derivative of the base compound) has not been previously approved or marketed in the United States for use in a drug product, either as a single ingredient or as part of a combination product, or as part of a mixture of stereoisomers.

New ester, salt, or other noncovalent derivative. A drug for which the active moiety has been previously approved or marketed in the United States, but for which the particular ester, salt, clathrate, or other noncovalent derivative, or the unmodified base compound is not yet approved or marketed in the United States, either as a single ingredient, part of a combination product, or part of a mixture of stereoisomers.

New formulation. A new dosage form or formulation, including a new strength, where the drug has already been approved or marketed in the United States by the same or another manufacturer. The indication may be the same as for the already marketed drug product or may be new.

New combination. A drug product containing two or more active moieties that have not been previously approved or marketed together in a drug product by any manufacturer in the United States. The new product may be a physical or a chemical (ester or noncovalent) combination of two or more active moieties.

New indication. The product duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by the same or another firm except that it provides for a new use.

Figure 3-1. New drug definitions.

Source: U.S. FDA, 1992. *Office of Drug Evaluation: Statistical Report*. Rockville, MD: U.S. FDA.

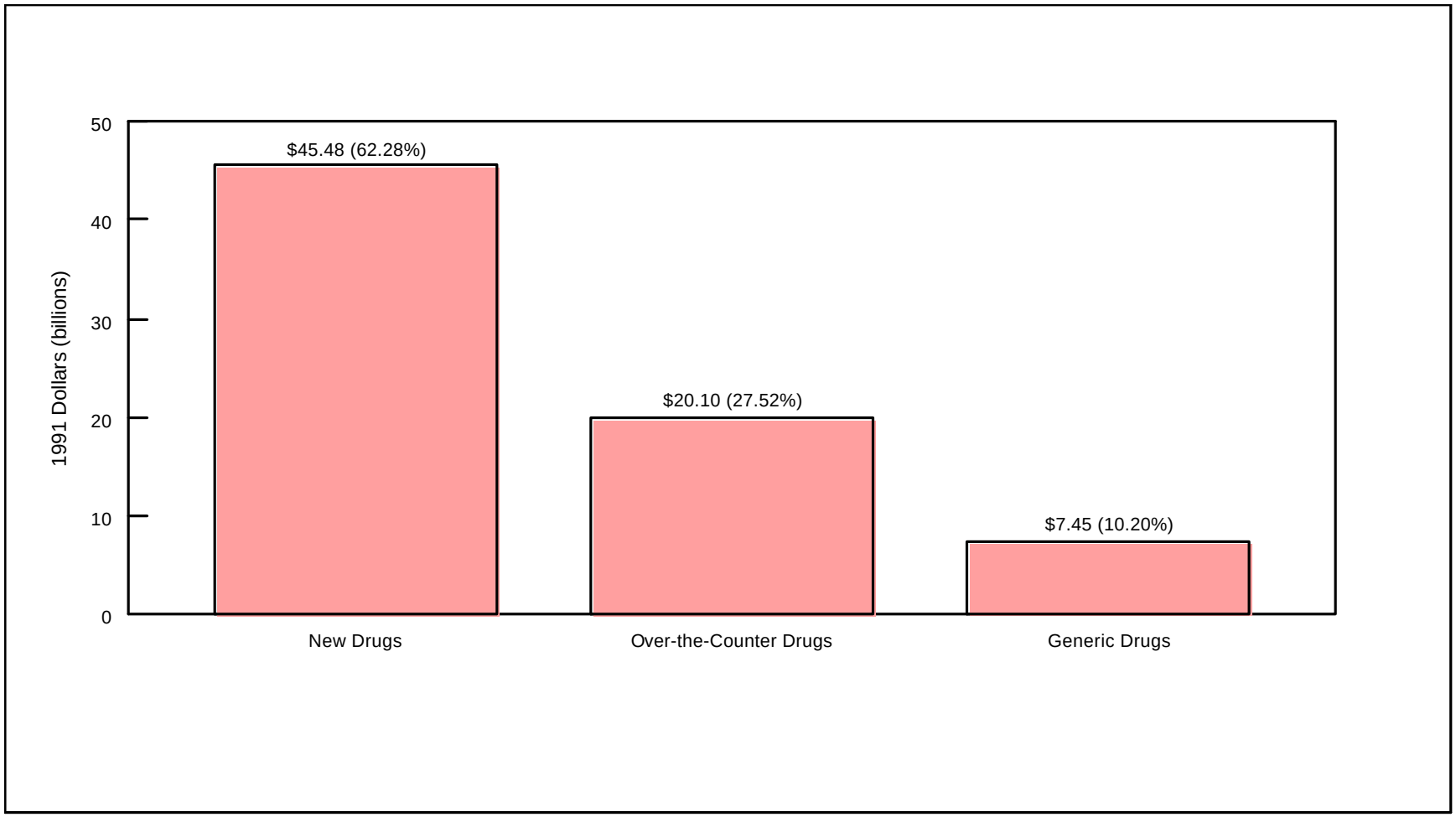

Figure 3-2. U.S. Drug Sales by Major Drug Type: 1991 (billions of dollars).

Source: NatWest, 1992. *The U.S. Generic Drug Industry*. New York: NatWest. U.S. Department of Commerce, 1993. *U.S. Industrial Outlook: 1993.* Washington, DC: U.S. Government Printing Office.

of total pharmaceutical sales.[2] Consistent with the observed trend toward greater use of generics, the trade association Pharmaceutical Research and Manufacturers of America (PhRMA) states that the generics share of the market (by number of prescriptions filled) rose from about 34 percent in 1991 to nearly 43 percent in 1995.[3]

Not surprisingly, the three major drug types face differing market conditions. For branded, patented drugs, the presence of patents and other barriers to market entry can create monopolistic conditions. In some therapeutic areas (e.g., HIV infection), monopolistic or semimonopolistic conditions prevail due to the lack of a wide array of effective drugs. In many therapeutic areas, however, competition ranges from moderate to intense due to the availability of several drugs (both branded, patented drugs and generic versions of branded drugs whose patents have expired) with similar therapeutic profiles. When AZT entered the human immunodeficiency anti-virus (HIV) market, for example, no approved alternatives were available and AZT enjoyed monopolistic conditions. When Biaxin® (clarithromycin) entered the upper respiratory anti-infective market, in contrast, the availability of a wide array of other broad-spectrum antibiotics (including a variety of branded and generic penicillins, cephalosporins, quinolones, and erythromycins, among others) meant that Biaxin® faced considerable competition in its market.

Even when multiple products compete intensely, purely classic competitive conditions rarely prevail in the prescription drug market because clinical considerations often outweigh unit price. In the treatment of upper respiratory infections, for example, physicians take into account the type of bacterium likely to be causing an individual patient's infection, the possibility of bacterial resistance to older antibiotics, the dosage schedule (patients are more likely to comply with therapy and show clinical improvement if they can take fewer doses), the likelihood of side effects, effectiveness in patients with concomitant diseases or in those taking other drugs, and so on. Due to factors such as these, the total cost of treatment (including the cost of retreatment if drug failure or relapse occurs, the cost of revisits to discuss side effects, etc.) is sometimes lower when higher unit-cost patented drugs are used than when low unit-cost generic drugs are used. In this

[2] NatWest, 1992. The NatWest Investment Banking Group. *The U.S. Generic Drug Industry*. New York: NatWest.

[3] PhRMA, 1996. *Generics' Share of U.S. Market, 1984-1995*. Document Number 5022. Pharmaceutical Research and Manufacturers of America.

context, Biaxin® garnered significant market share despite the availability of inexpensive generic penicillins and erythromycins.

In the OTC market, on the other hand, consumers make drug choices themselves. Because of this, and because of the availability of many branded and generic versions of products in most categories (e.g., analgesics, cough/cold remedies, etc.), price plays a more central role. Competition among and within the three drug groups and other issues concerning market structure in the pharmaceutical industry are discussed in more detail in Section 3.3. The following three subsections examine the major drug groups and regulations that affect their manufacture and sale.

3.1.2.1 New Drugs

About 90 percent of all drugs marketed since 1938 were new drugs at the time of their introduction. This "new" drug status is not permanent, however. Although most of those introduced in the 1980s and 1990s are currently available as branded drugs, with no generic equivalents yet on the market, many of the older drugs, although "new" when first introduced, are now old enough to have lost their patent protection. Despite the availability of generic equivalents, many of these off-patent branded products remain on the market. Other formerly "new" branded drugs are no longer available, however, having been entirely supplanted by generic equivalents or newer drugs with improved therapeutic profiles.

The process of bringing a new drug to market is lengthy and complex (see Figure 3-3). The process begins with discovery experiments in which scientists screen existing substances for therapeutic or diagnostic potential, modify existing substances to create new substances with desired therapeutic or diagnostic properties, or attempt to create (through chemical synthesis, genetic manipulation, or biological processes) entirely new substances with therapeutic or diagnostic properties. When a drug seems to hold promise, scientists conduct more extensive laboratory investigations to characterize the drug's physical properties as well as preclinical animal studies to determine how it affects living systems. If these studies are successful, the sponsoring pharmaceutical firm designs and initiates clinical studies in which the drug is given to humans. At this point, FDA becomes directly involved for the first time. It should be noted that very few substances

It takes 15 years on average for an experimental drug to travel from lab to medicine chest.
Only five in 5,000 compounds that enter preclinical testing make it to human testing.
One of these five tested in people is approved.

	Early Research/ Preclinical Testing		Clinical Trials: Phase I	Clinical Trials: Phase II	Clinical Trials: Phase III		Phase III		Phase IV
Years	6.5		1	2	3		2.5*	15 Total	Additional post-marketing testing required by FDA
Test Population	Laboratory and animal studies	File IND at FDA	20 to 80 healthy volunteers	100 to 200 patient volunteers	1,000 to 3,000 patient volunteers	File NDA at FDA	Review process/ approval		
Purpose	Assess safety and biological activity		Determine safety and dosage	Evaluate effectiveness, look for side effects	Verify effectiveness, monitor adverse reactions from long-term use				
Success Rate	5,000 compounds evaluated		5 enter trials				1 approved		

* Average for 1990-1994. In 1994, the average approval time was 1.5 years.

Figure 3-3. The drug development and approval process in the 1990s.

Source: Beary, John F., 1996. *The Drug Development and Approval Process*. Pharmaceutical Research and Manufacturers of America.

make it this far. PhRMA estimates that of about 5,000 substances screened, only 5 make it to human testing—and just 1 makes it to market.[4]

Before any new drug can be tested on humans, the drug's sponsor must submit an investigational new drug (IND) application to FDA that summarizes the preclinical work, lays out a plan for how the drug will be tested in humans, and provides assurances that appropriate measures will be taken to protect study participants. Unless FDA decides that the proposed study is unsafe, clinical testing may begin 31 days after the IND application is submitted to FDA. While clinical trials progress through several phases aimed at establishing safety and efficacy, the manufacturer develops the processes necessary to produce large quantities of the drug that meet quality standards for commercial marketing.

When all this work has been done, the pharmaceutical firm submits a new drug application (NDA) that includes the information FDA needs to determine whether the drug is safe and effective for its intended use and whether the manufacturing process can ensure its quality. Because they have never been marketed before, new drugs receive the most scrutiny from FDA and undergo a lengthy review process.[5] Throughout this process, drug sponsors typically interact with FDA to answer questions and address concerns. After completing its review, FDA responds to each NDA with an approval letter (approving the drug for manufacture and sale), an approvable letter (indicating that the drug will be approved if certain issues are addressed), or a not approvable letter (indicating that the drug may not be manufactured or sold).

According to FDA data, the agency has approved an average of 90 new drugs each year since 1982 (see Figure 3-4). Approximately 26 percent of the new drugs approved each year are NMEs. The agency also approves, on average, some 1,207 new drug supplements, which describe proposed changes to an already

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[4] Moore, Judy, 1996. *The Pharmaceutical Industry.* National Health Policy Forum background paper. Washington, DC: The George Washington University.

[5] Under pressure to review NDAs faster, FDA has begun receiving payments from new drug sponsors to help cover reviewing expenses; authorized by the Prescription Drug User Fee Act of 1992, this program was expected to bring in $300 million over 5 years, at which point the program expired to allow time for a review of the program's effectiveness in speeding drug reviews (U.S. Department of Commerce, 1994. *U.S. Industrial Outlook: 1994.* Washington, DC: U.S. Government Printing Office). This program was reauthorized under the FDA Modernization Act of 1997. Citing FDA sources, PhRMA states that FDA's average review time for NDAs declined from about 30 months to about 19 months between 1992 and 1995 (PhRMA, 1996. FDA Approves 28 New Drugs; Review Time is 19.2 Months. *New Drug Approvals in 1995.* Pharmaceutical Research and Manufacturers of America).

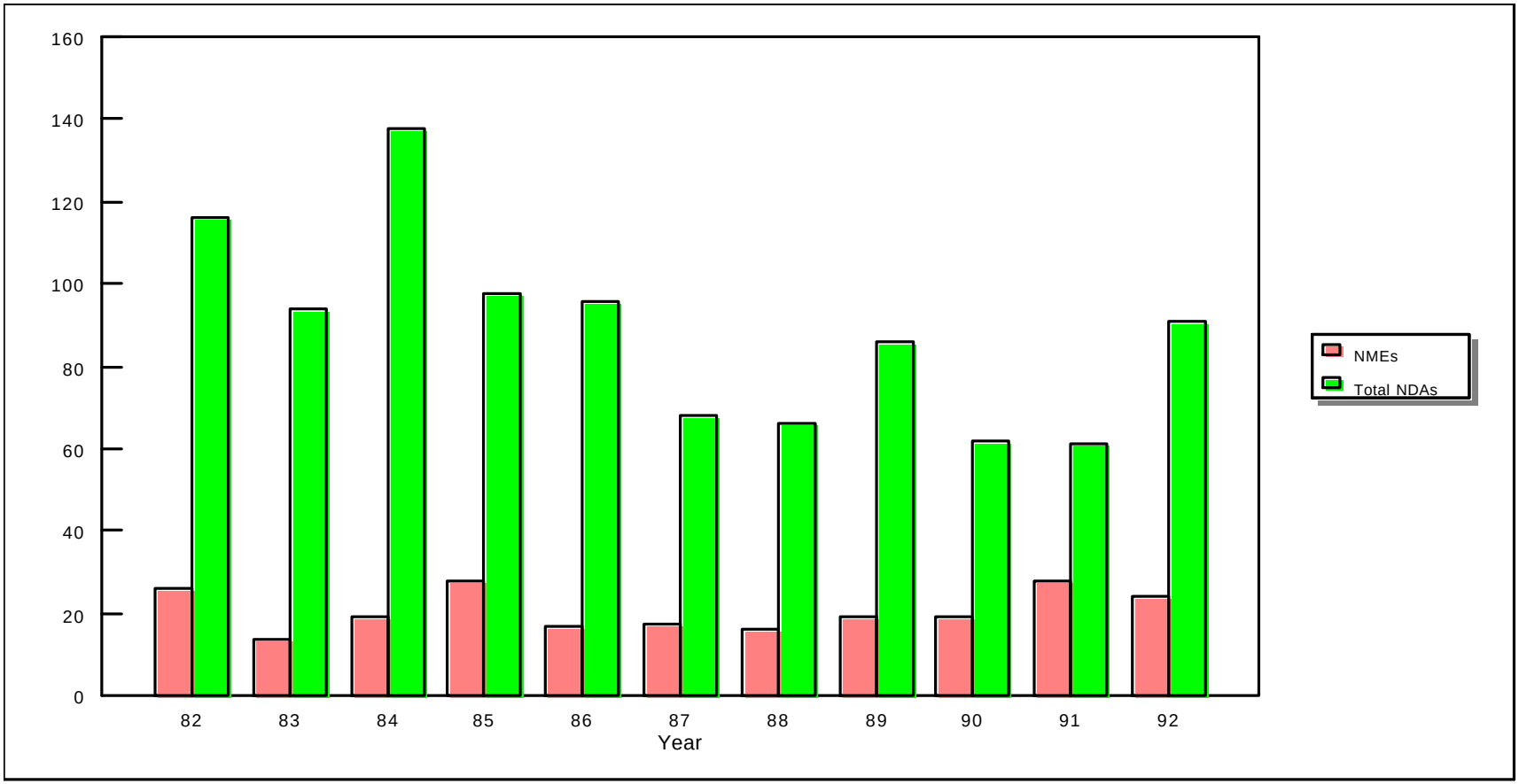

Figure 3-4. Number of Approved New Drug Applications (NDAs) and New Molecular Entities (NMEs): 1982-1992.

Source: U.S. FDA, 1992. *Office of Drug Evaluation: Statistical Report*. Rockville, MD: U.S. FDA.

approved drug (e.g., a new indication, revision of an approved indication, etc.). FDA approves approximately 60 percent of all NDAs and supplements received each year.[6] Figure 3-5 presents a breakdown of new drugs approved between 1987 and 1992 by major therapeutic category.

To prioritize NDAs for review, FDA classifies new drugs according to their potential therapeutic importance. Type A drugs represent drugs that might provide effective therapy or diagnosis for a disease that is not adequately treated or diagnosed by any marketed drug. Type B drugs have modest advantages over currently marketed drugs such as greater patient convenience and fewer side effects. Type C drugs have substantially equivalent therapeutic benefits as already marketed drugs. Approximately 22 percent of the new drugs approved by FDA between 1987 and 1992 were classified as either Type A or B, representing potentially significant therapeutic gains.[7]

3.1.2.2 Generic Drugs

When the patent on a prescription drug runs out, other manufacturers often enter the market with a generic version of the drug. To gain market approval, manufacturers of generic drugs must prove to FDA through an abbreviated NDA (ANDA) that their product is "bioequivalent" to a previously marketed drug—that is, that it contains identical active chemical ingredients and enters the bloodstream at the same rate and levels. Because demonstrating bioequivalence is generally much easier than proving the overall safety and effectiveness of a drug (FDA assumes that bioequivalence implies identical safety and effectiveness), generic drugs are generally approved much more quickly than new drugs.[8] Nonetheless, bioequivalence testing may take several years to complete. In the early 1990s, FDA approved an average of about 240

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[6] U.S. FDA, 1992. U.S. Food and Drug Administration. *Office of Drug Evaluation: Statistical Report.* Rockville, MD: U.S. FDA.

[7] U.S. FDA, 1992. *Op. cit.*

[8] Before 1984, manufacturers of generic drugs would often need to duplicate many of the original manufacturer's clinical tests to gain market approval. The 1984 Drug Price Competition and Patent Term Restoration Act (the 1984 Price Act) rescinded these strict controls for generics, stipulating that generic drug manufacturers need only demonstrate bioequivalence to a previously marketed drug. It is generally agreed that the 1984 Price Act has greatly facilitated the entry of generics into the pharmaceutical market.

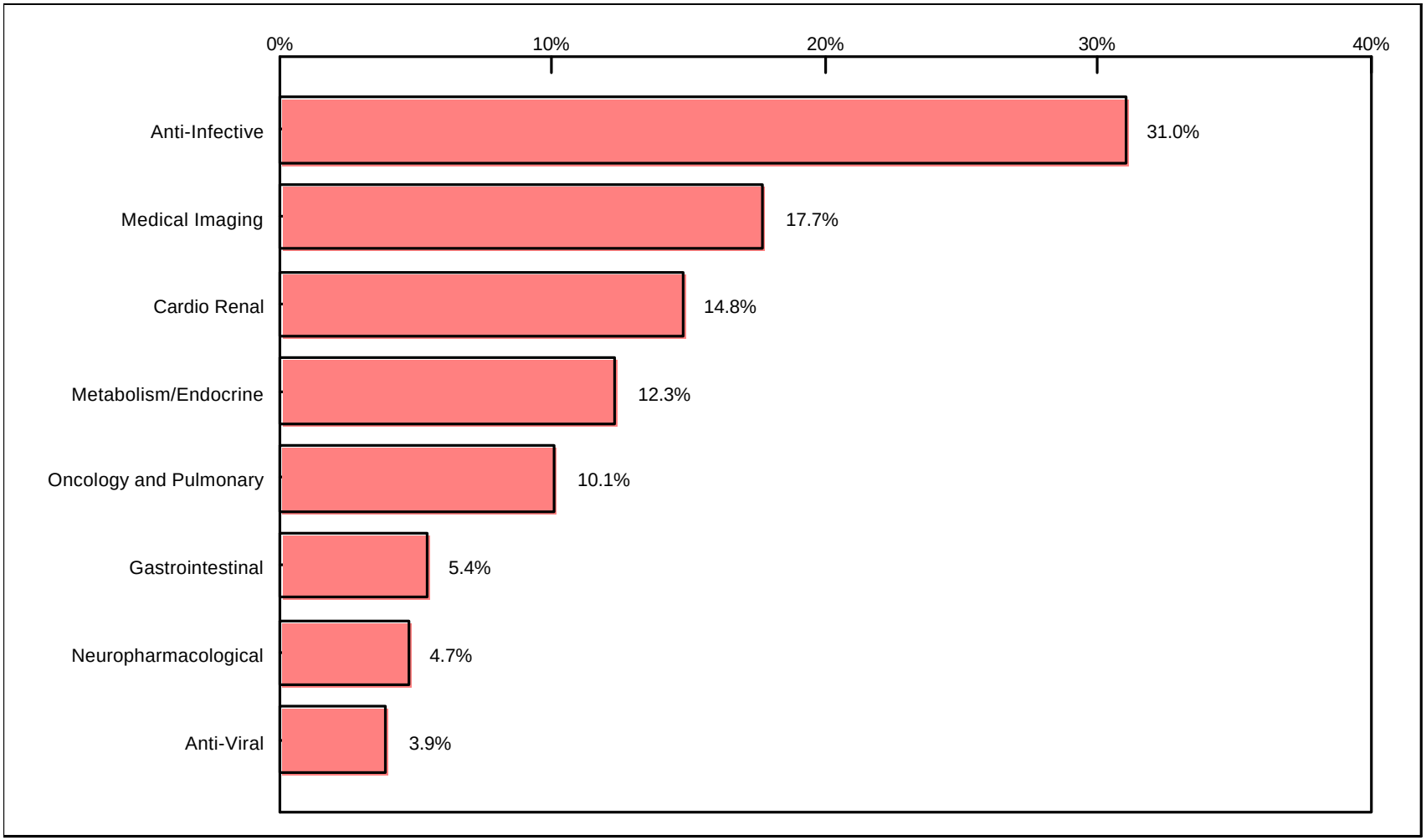

Figure 3-5. Approved NDAs by therapeutic category: 1987-1992.

Source: U.S. FDA, 1992. *Office of Drug Evaluation: Statistical Report*. Rockville, MD: U.S. FDA.

ANDAs per year.[9] An industry analyst places the current approval rate at 250 ANDAs per year.[10] The FDA web site reports 254 ANDAs approved in 1997.[11]

Since 1980, generic drugs have captured an increasing share of the prescription drug market. As shown in Figure 3-6, generic drugs accounted for 19.1 percent of prescription drug sales in 1991 (the most recent year for which sales data are available), almost double their market share in 1980. With rising health care costs, public and private insurers have put increasing pressure on health care providers to use less expensive generic drugs when available. According to industry analysts, the generic drug industry is poised to accumulate even greater market share over the next decade. Brand-named drugs representing annual sales of over $20 billion in 1992 were projected to lose patent protection between 1992 and 1996,[12] and PhRMA states that the generics share of the market (by number of prescriptions filled) rose from about 34 percent in 1991 to nearly 43 percent in 1995, suggesting that the predicted trend toward greater use of generics is occurring.[13]

3.1.2.3 OTC Drugs

FDA treats OTC drugs somewhat differently than other regulated pharmaceutical products. Before 1976, OTC drugs were not subject to the same NDA requirements. In 1976, however, FDA revised its OTC policy, calling for more rigorous regulation of the OTC market. In the same year, FDA embarked on an extensive review of all FDA approved ingredients of OTC drugs. FDA divided the previously broad grouping of OTC drugs into distinct therapeutic categories (e.g., sleeping aids, cough suppressants), each with their own monograph standard requiring specific labeling and dosages. In its review of OTC ingredients, FDA has removed many previously approved ingredients from the list of approved OTC ingredients. Once FDA's

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[9] Sherwood, Ted, 1993. U.S. Food and Drug Administration, Center for Drug Evaluation, Office of Generic Drugs. Telephone conversation. May 19, 1993.

[10] Moore, 1996. *Op. cit.*

[11] http://www.fda.gov/cder/da/da.htm

[12] NatWest, 1992. *Op. cit.*

[13] PhRMA, 1996. *Generic's Share of U.S. Market, 1984-1995. Op. cit.*

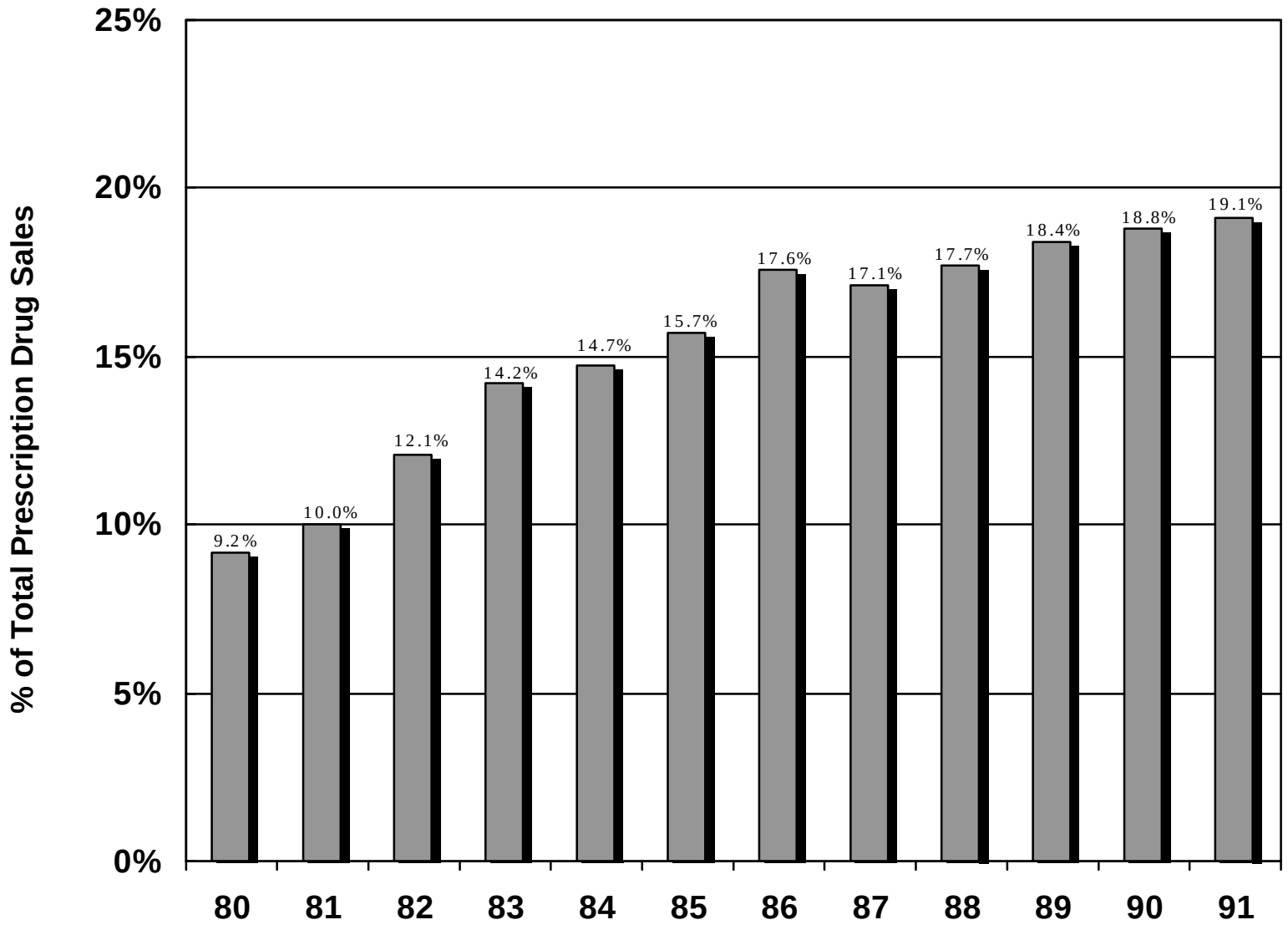

Figure 3-6. Generic prescription drug sales as a percentage of total prescription drug sales: 1980-1991.

Source: NatWest, 1992. *The U.S. Generic Drug Industry*. New York: NatWest.

review is complete, new OTC drugs that have not been monographed will have to submit safety and effectiveness data to FDA, much like that required in an NDA.

Like generics, OTC drugs are a growing segment of the overall pharmaceutical market. OTC trade organizations expect the OTC market share to continue to increase over the next decade as FDA increasingly grants OTC status to prescription drugs and as the move to control health care costs leads to greater use of less expensive OTC products. Within the OTC market itself, analgesics account for approximately 39 percent of total sales, cold medications 19 percent, and antacids 14 percent. Other OTC products such as antinausea drugs and cough medicines make up the remainder of the OTC market.

3.1.3 Manufacturing Processes

The pharmaceutical industry uses an array of complex batch-type processes and technologies in the manufacture of its products.[14] Rather than detailing specific processes and technologies, this section will describe the three main stages of pharmaceutical production: R&D, bulk drug manufacturing (via fermentation, extraction, and chemical synthesis), and finished pharmaceutical product formulation. These manufacturing processes roughly correspond to the EPA's subcategorization scheme described in Section Two (see Figure 3-7). As noted earlier, some pharmaceutical companies engage in all three stages of pharmaceutical manufacturing, while others focus on just one or two.

[14] For a detailed discussion of pharmaceutical manufacturing processes, please refer to EPA's 1982 and 1983 proposed and final development documents (U.S. EPA, 1982. U.S. Environmental Protection Agency. *Proposed Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category*. Washington, DC: U.S. EPA; U.S. EPA, 1983. *Development Document for Effluent Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category*. Washington, DC: U.S. EPA), as well as the 1995 and 1998 development documents for the current final rule. These sources are the basis for much of the discussion in Section 3.1.3.

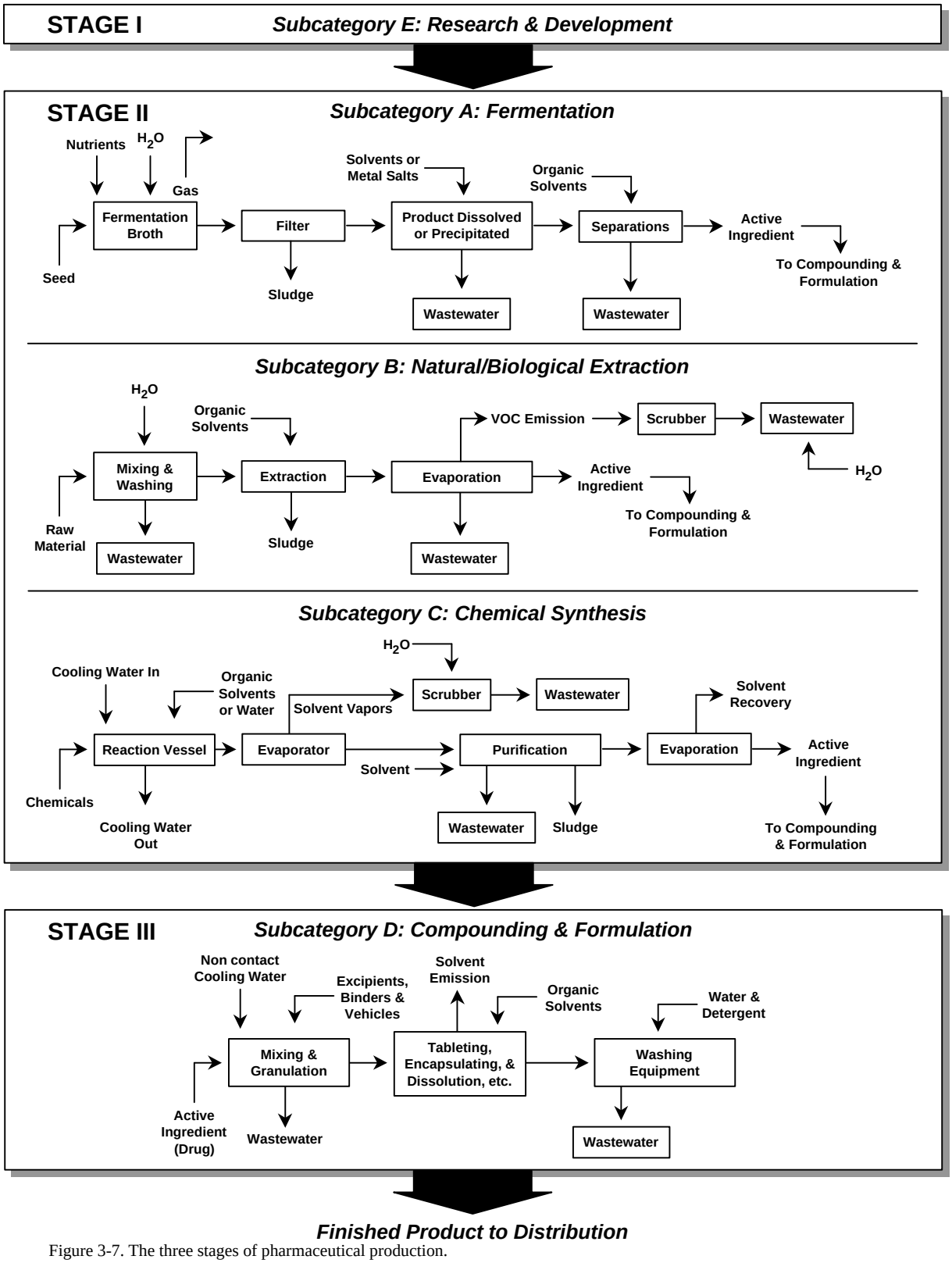

Figure 3-7. The three stages of pharmaceutical production.
Source: Adapted from EPA, 1992. *Pharmaceutical Manufacturing Industry: Revision of Effluent Guidelines.* Unpublished Status Briefing. Washington, DC: U.S. EPA.

3.1.3.1 Stage I—R&D

Stage I—R&D—is aimed at discovering, enhancing, and devising reliable manufacturing processes for drugs. As such, it serves the dual purpose of product development and manufacturing method development/manufacturing initiation. Corresponding to EPA's pharmaceutical industry subcategory E, pharmaceutical R&D encompasses several fields, including chemical, microbiological, and pharmacological research. A typical innovative pharmaceutical company employs specialized personnel with expertise in medicinal, organic, and analytical chemistry; microbiology; biochemistry; physiology; pharmacology; toxicology; chemical engineering; and pathology. The development of a new drug involves innumerable laboratory processes and years of experimental testing. The entire R&D process can take as long as 12 years to complete.[15]

3.1.3.2 Stage II—Bulk Drug Manufacturing

Stage II is aimed at converting organic and chemical substances into bulk active ingredients via one (or more) of three conversion processes—fermentation, extraction, or chemical synthesis. EPA's pharmaceutical industry (subcategories A, B, and C) correspond to these three conversion processes, respectively. The processes are defined as follows:[16]

- ***Fermentation (Subcategory A)***. Fermentation is the decomposition of complex substances (creating new substances) through the action of enzymes or ferments produced by microorganisms (usually bacteria, molds, or yeasts). The process begins in the laboratory with a carefully maintained population of a microbial strain. A few cells from this culture are grown into a dense suspension and then transferred to a seed tank designed for maximum cell growth. Material from the seed tank is then transferred to a vessel containing substances to be fermented. Following fermentation, the fermenter broth is filtered to remove solid residues. The filtrate is then processed to recover the desired product using solvent extraction, precipitation, and ion exchange or adsorption chromatography. Steroids, Vitamin B_{12}, and antibiotics are typically produced using a batch fermentation process.

[15] See Section 3.2.3 for a more detailed discussion of pharmaceutical R&D.

[16] Definitions adapted from U.S. EPA, 1991. *Guides to Pollution Prevention: The Pharmaceutical Industry*.

- ***Extraction (Subcategory B)***. Biological, or natural, extraction produces pharmaceuticals from natural material sources such as roots, leaves, and animal glands. Product recovery and purification processes include precipitation and solvent extraction. The amount of finished drug product is quite small compared with the volume of natural source material used. During each process step, the volume of material worked greatly diminishes to the point where final purification might occur on volumes of less than one-thousandth of the initial volume. Anticancer drugs, insulin, morphine, and hormones are examples of drugs manufactured using natural extraction processes.

- ***Chemical Synthesis (Subcategory C)***. Chemical synthesis takes place in a series of reaction, separation, and purification steps. Numerous types of chemical reactions, recovery processes, and chemicals are used to produce drugs through chemical synthesis. Chemicals used in chemical synthesis operations range widely and include organic and inorganic reactants and catalysts and a variety of solvents listed as priority pollutants by EPA. Most drugs today are produced by chemical synthesis. Examples include aspirin and acetaminophen.

A substance that is fermented, naturally extracted, or chemically synthesized might require no further processing to become a bulk active ingredient. Alternatively, additional chemical synthesis might be necessary before the desired active ingredient is formed. In either case, when large-scale production is undertaken, these conversion processes often involve discharges of process wastewater. Of the facilities included in the Section 308 Survey, 59 percent were engaged in one or more of the above processes.

3.1.3.3 Stage III—Finished Pharmaceutical Product Formulation

Stage III—formulation—refers to the combining of bulk active ingredients with other substances to produce dosage forms suitable for human or animal intake. Formulation corresponds to EPA subcategory D and can be defined as the preparation of dosage forms into tablets, capsules, liquids, parenterals (introduced internally other than by way of the intestines), and creams and ointments. Tablets account for 90 percent of all medications taken orally and are produced by blending active ingredients with fillers such as starch or sugar and binders such as corn starch. Hard and soft capsules consist of gelatin capsules that are filled with an active ingredient. Liquid dosage forms include syrups, elixirs, suspensions, and tinctures, all of which are prepared by mixing solutes with a selected solvent in a glass-lined or stainless steel vessel. Parenterals are injected into the body and are prepared as solutions, dry solids, suspensions, dry insoluble solids, and emulsions. Ointments and creams are semisolid dosage forms prepared for topical use. Like bulk

manufacturing, formulation (finished dosage form manufacturing) often involves discharges of process wastewater. Approximately 68 percent of the surveyed facilities had formulating operations.

Following formulation, finished drugs are distributed to hospitals, health maintenance organizations (HMOs), retail pharmacies, as well as directly to consumers.

3.2 FACILITY, OWNER COMPANY, AND PARENT COMPANY CHARACTERISTICS

This section presents facility, owner company, and parent company data for the pharmaceutical industry garnered from the U.S. Department of Commerce and the Section 308 Pharmaceutical Survey. The data cover numbers of establishments and employees, value of shipments, international trade, production costs, and baseline financial conditions. For the purpose of this EA, a facility is defined as an individual location where pharmaceutical products are manufactured and/or formulated. An owner company might control one or several individual facility locations. Owner companies might, in turn, be owned by a parent company. The U.S. Department of Commerce collects data only at the facility level; the Section 308 Pharmaceutical Survey collected financial data at all three levels. As discussed in Section Two, U.S. Department of Commerce data are more representative of the industry as a whole, whereas the survey data are more representative of the regulated community, since discharging facilities and their firms were the primary target of the survey. Each of the following sections begins by discussing U.S. Department of Commerce data, where available, and then follows with parallel survey data.[17]

[17] The following discussions use these sources: U.S. Bureau of the Census, 1997. *County Business Patterns:1995.* Washington, DC: U.S. Government Printing Office; U.S. Bureau of the Census, 1996. *County Business Patterns: 1994.* U.S. Government Printing Office.

Table 3-1

Number of Pharmaceutical Establishments by Employee Size:
SIC 283 Drugs

SIC Code	Total Number of Establishments		Number of Employees							
			1-19		20-99		100-249		>250	
	1990	1995	1990	1995	1990	1995	1990	1995	1990	1995
283 Drugs	1,343	1,529	623	765	416	419	141	165	154	180
2833 Medicinals and Botanicals	266	261	133	169	68	60	13	21	12	11
2834 Pharmaceutical Preparations	680	711	288	309	202	187	78	95	112	120
2835 Diagnostic Substances	161	251	60	99	56	89	26	32	19	31
2836 Biological Products, Except Diagnostics	220	284	97	167	88	82	24	17	11	18

Sources: U.S. Bureau of the Census, 1997. *County Business Patterns: 1995.* Washington, DC: U.S. Government Printing Office; U.S. Bureau of the Census, 1993. *County Business Patterns: 1990.* Washington, DC: U.S. Government Printing Office.

3.2.1 Number of Establishments and Employees

3.2.1.1 U.S. Department of Commerce Data

In 1990, the U.S. Department of Commerce classified some 1,343 establishments (i.e., facilities) involved in producing SIC 283 drugs. In 1995, that number grew to 1,529 (see Table 3-1).[18] Approximately half of these establishments (51 to 47 percent in 1990 and 1995, respectively) were producing SIC 2834 drugs (pharmaceutical preparations), with the remaining establishments divided among SICs 2833, 2835, and 2836. Between 1990 and 1995, the number of establishments in SICs 2835 and 2836 (diagnostic substances; biological products, except diagnostics) grew faster than the number of establishments in SICs 2833 and 2834 (medicinals and botanicals; pharmaceutical preparations).

Together, SIC 283 pharmaceutical establishments employed 218,000 people in 1995,[19] an increase of 11 percent over 1989 employment levels (see Table 3-2). In contrast to the substantial growth that occurred in the 1980s, however, pharmaceutical employment remained relatively steady between 1989 and 1992, but by 1995 has increased somewhat over 1992 levels. Due to cost pressures arising from the advent of price discounting, weak foreign economies, increased use of generic and OTC drugs, and the previous anticipation of increased government controls under health care reform, many pharmaceutical firms underwent significant restructuring in the early to mid 1990s—including substantial job cuts. These trends disproportionately affected establishments in SIC 2834 (pharmaceutical preparations), while those in SIC 2835 (diagnostic substances) fared significantly better than other SIC 283 industries. Although employment remained heavily concentrated in SIC 2834, this sector's share of total industry employment dropped from 80 percent to 70 percent between 1990 and 1991. With continued investment in R&D to discover and bring to

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[18] In reality, there are probably more establishments manufacturing pharmaceuticals than are indicated by U.S. Department of Commerce data. Because U.S. Department of Commerce classifies facilities by their primary line of business, the four pharmaceutical SIC codes do not capture facilities that manufacture pharmaceuticals but whose primary business is classified in some other SIC code.

[19] PhRMA puts industry employment much higher than that for equivalent years shown in Table 3-2—213,651 in 1992 and 208,460 in 1994 (PhRMA, 1996. *Summary of Industry Employment Statistics from Various Sources.* Document Number 5090. Pharmaceutical Research and Manufacturers of America). PhRMA's employment data are based on the association's annual members survey. Because PhRMA's members include large corporations that also engage in activities outside the pharmaceutical industry, however, PhRMA's data may overstate employment in this industry.

Table 3-2

Total Number of Employees and Production Workers:
SIC 283 Drugs
(1989-1995)

SIC Code		1989	1990	1991	1992	1993	1994	1995
Total Employment								
283	Drugs	196,000	194,000	203,000	194,000	218,000	205,000	218,000
2833	Medicinals and Botanicals	11,400	11,700	13,700	13,100	13,000	12,900	14,300
2834	Pharmaceutical Preparations	142,000	155,000	142,000	123,000	128,000	133,000	142,000
2835	Diagnostic Substances	16,100	16,000	33,500	39,900	39,300	39,100	39,800
2836	Biological Products, Except Diagnostics	14,500	14,300	13,300	18,500	19,000	19,800	21,100
Production Workers								
283	Drugs	82,800	86,800	90,100	92,700	94,600	102,000	113,000
2833	Medicinals and Botanicals	6,600	6,900	7,800	7,500	7,700	7,500	7,700
2834	Pharmaceutical Preparations	62,400	65,700	64,600	62,400	62,800	68,000	78,300
2835	Diagnostic Substances	6,800	7,000	10,800	14,700	14,900	16,100	15,600
2836	Biological Products, Except Diagnostics	7,000	7,200	6,900	8,100	9,200	9,900	11,000

Source: U.S. Department of Commerce, 1994. *U.S. Industrial Outlook: 1994.* Washington, DC: U.S. Government Printing Office; U.S. Bureau of the Census, 1997. *Statistical Abstract of the United States: 1997*. Washington, DC.

market new drugs, more experience in competing with generics and OTCs, improving economies, and a leveling of concern about health care reform, pharmaceutical industry employment (including SIC 2834 employment) has begun to grow again and is expected to continue growing for the next few years, albeit at a slower pace than that seen in the 1980s, as is evidenced by the general growth in employment between 1992 and 1995. Throughout the 1980s and 1990s, the proportion of the industry's workforce involved in production has remained about the same: between 45 and 46 percent.

Smaller establishments (less than 100 employees) dominate the pharmaceutical industry, accounting for 77 percent of all establishments in SIC 283 in both 1990 and 1995. In fact, about half of all establishments (46 percent in 1990, 50 percent in 1995) employ fewer than 20 people. The industry, however, does have an unusually high percentage of establishments with more than 250 employees (11 and 12 percent in 1990 and 1995, respectively) when compared to the manufacturing sector overall, in which only 4 percent of establishments have more than 250 employees. As discussed in Section 3.3, the presence of an unusually high percentage of large facilities and firms in the industry can be attributed to the enormous financial commitment necessary to develop and market new products and the existence of economies of scale in pharmaceutical manufacturing. With the pharmaceutical industry firm restructuring that occurred in the early 1990s—which included a number of company mergers/consolidations (especially among larger firms) and sales of R&D or other divisions (especially among smaller firms) as well as job cuts—many large firms became even larger, while many smaller firms became even smaller.

3.2.1.2 Section 308 Pharmaceutical Survey Data

EPA estimates that approximately 286 of the industry's 1,343 establishments are either direct or indirect dischargers and therefore potentially would be affected by revised effluent regulations. The Section 308 Survey censused or sampled 244 of these establishments to represent the 286 facilities. Of the 286 facilities, 73 percent are owned by other companies. Only 27 percent of the surveyed facilities indicated that they were independently owned. In 1990, 69 parent companies owned 56 percent of the surveyed establishments.

Employment data were collected at the facility level only (see Table 3-3). According to the survey data, only 6 percent of all establishments had fewer than 20 employees. This pattern is in contrast to U.S.

Table 3-3

Surveyed Facilities by Number of Employees

Number of Employees	Number of Facilities	Percentage of All Facilities
1-19	18	6%
20-99	57	20%
100-249	55	19%
250-500	54	19%
501-999	57	20%
>1000	45	16%
Total	286	100%

Source: Section 308 Pharmaceutical Survey.

Department of Commerce data, which indicate that roughly half of all pharmaceutical establishments employ fewer than 20 employees. Conversely, where U.S. Department of Commerce reports that only 11 percent of pharmaceutical establishments have more than 250 employees, nearly 55 percent of the surveyed establishments reported employment of over 250 people. The fact that surveyed establishments include a much higher proportion of large facilities than the pharmaceutical industry as a whole makes sense, since we would expect most dischargers to be major bulk drug manufacturers or vertically integrated pharmaceutical firms that engage in a great deal of large-scale manufacturing (typically at a large facility) rather than exclusively R&D or marketing firms (typically smaller facilities or firms). In the surveyed facilities, approximately 70 percent of manufacturing employment is concentrated in pharmaceutical manufacturing. Over 50 percent of the surveyed facilities reported no employment in nonpharmaceutical-related activities.

3.2.2 Value of Shipments

3.2.2.1 U.S. Department of Commerce Data

According to the U.S. Department of Commerce, drug industry shipments increased about 6 percent in 1993 to $69 billion, an estimate that includes all products shipped by establishments classified in SICs 2833 through 2836. Shipments of drug products alone totaled about $58.4 billion in 1993. In current dollars, drug industry shipments grew at a rate of 9 to 12 percent between 1987 and 1991; since 1991, these shipments have grown at a slower pace, between 2.1 and 7.4 percent annually. In real terms, growth in most years has averaged about 2 percent annually. Table 3-4 lists total industry shipments ($1990) and drug product shipments between 1987 and 1994. The data indicate that the industry performed well despite the recession in the early 1990s and the various cost pressures and trends described above. Sales data from PhRMA (based on PhRMA's annual survey of its members) generally agree with these Department of Commerce data and trends. PhRMA data suggest that industry performance has continued to be strong, with estimated 3.7 percent and 8.8 percent increases in sales in 1995 and 1996, respectively.[20]

[20] PhRMA, 1996. *Growth in Domestic U.S. Sales and Sales Abroad, Ethical Pharmaceuticals, PhRMA Member Companies, 1970-1996.* Document Number 5060. Pharmaceutical Research and Manufacturers of America.

Table 3-4

Value of Shipments: SIC 283 Drugs
(millions of 1990 dollars)

Code		1987	1988	1989	1990	1991	1992	1993	1994	1995
Industry Shipments†										
283	Drugs	$42,168	$46,054	$50,342	$56,715	$63,468	$64,335	$64,454	$6,6329	$69,965
2833	Medicinals and Botanicals	$3,598	$4,345	$4,872	$5,194	$6,581	$6,193	$5,381	$5,331	$6,088
2834	Pharmaceutical Preparations	$34,469	$37,509	$41,029	$46,646	$49,426	$45,777	$48,379	$49,108	$50,121
2835	Diagnostic Substances	$2,368	$2,367	$2,383	$2,599	$4,952	$6,507	$6,233	$7,243	$8,370
2836	Biological Products, Except Diagnostics	$1,733	$1,832	$2,058	$2,276	$2,510	$3,789	$4,462	$4,646	$5,386
Product Shipments††										
283	Drugs	$37,894	$41,390	$44,891	$47,831	$50,791	$57,693	$58,085	$59,282	$61,775
2833	Medicinals and Botanicals	$4,537	$5,181	$5,528	$5,789	$6,507	$6,645	$6,128	$5,926	$6,339
2834	Pharmaceutical Preparations	$28,579	$30,944	$33,531	$35,280	$36,630	$40,885	$41,334	$42,075	$42,848
2835	Diagnostic Substances	$2,882	$3,207	$3,558	$4,234	$4,869	$5,880	$5,859	$6,282	$7,154
2836	Biological Products, Except Diagnostics	$1,896	$2,058	$2,276	$2,529	$2,784	$4,282	$4,763	$5,001	$5,434

† Value of all products and services sold by establishments in the pharmaceutical industry.
†† Value of products classified in the pharmaceutical industry produced by all industries.

Source: U.S. Bureau of the Census, 1997. *Statistical Abstract of the United States: 1997*. Washington, DC: U.S. Government Printing Office; U.S. Department of Commerce, 1994. *U.S. Industrial Outlook: 1994*. Washington, DC: U.S. Government Printing Office.

Table 3-5

Value of Shipments by Employee Size of Establishment: SIC 283
(millions of 1990 dollars)

Employee Size	Number of Establishments		Number of Employees		Value of Shipments		Value of Shipments Per Employee	
	1987	1992	1987	1992	1987	1992	1987	1992
<20 employees	696	702	4,800	5,000	$813	$1,088	$0.17	$0.22
20-99 employees	390	421	17,200	19,600	$2,815	$4,440	$0.16	$0.23
99-500 employees	200	219	43,200	55,600	$13,034	$21,254	$0.30	$0.38
>500 employees	70	80	104,700	113,900	$25,505	$37,436	$0.30	$0.33

Source: U.S. Department of Commerce, 1995. *U.S. Census of Manufactures: 1992.* MC92-S-2. Washington, DC: U.S. Government Printing Office; U.S. Department of Commerce, 1991. *U.S. Census of Manufactures: 1987.* MC87-S-6 (CD-ROM). Washington, DC: U.S. Government Printing Office.

tend to ship a greater proportion of the relatively expensive finished, branded pharmaceutical products than do smaller establishments, which are more likely to ship bulk, generic, and OTC pharmaceutical products.

The data in Table 3-5 also show that shipments per employee ($1990) generally increase across size classes, indicating the possible presence of economies of scale (see Section 3.3.1). Although the number of employees increased in all size classes between 1987 and 1992, the value of shipments increased even more—so that the value of shipments per employee increased substantially between 1987 and 1992. This suggests that employee productivity rose during this time.

A large majority of industry shipments is attributed to SIC 2834 Pharmaceutical Preparations, which in 1995 had sales totaling $45 billion (see Table 3-4). Like this sector's share of total pharmaceutical employment (see Section 3.2.1.1), SIC 2834 establishments' share of industry shipments has declined somewhat in recent years—from about 80 percent in the late 1980s to about 74 percent in the early 1990s. The U.S. Department of Commerce further breaks down SIC 2834 shipments into five-digit SIC codes representing individual therapeutic categories. Table 3-6 presents value of shipments data for nine therapeutic categories within SIC 2834. As can be seen in 1996, 77 percent of SIC 2834 shipments are for prescription drugs, 21 percent are for OTC drugs, and 2 percent are for bulk shipments. Because prescription products typically cost more per unit than OTC and bulk drugs, shipment data for these three product groups would be somewhat closer if reported by shipment volume rather than shipment value. OTC drugs account for the greatest portion of shipments in SICs 28349, pharmaceutical preparations for veterinary use; 28346, pharmaceutical preparations acting on the skin; and 28344, pharmaceutical preparations acting on the respiratory system.

3.2.2.2 Section 308 Survey Data

The Section 308 Survey collected data on pharmaceutical and nonpharmaceutical revenues at the facility, owner company, and parent company levels.[21] Only 212 facilities reported revenues for all 3 years

[21] Unless otherwise noted, all revenue data is reported in 1990 dollars.

Table 3-6

Value of Product Shipments by Prescription/Nonprescription: SIC 2834 Pharmaceutical Preparations (millions of 1990 dollars)

SIC Code	Product Description	1993				1994			
		Total	Prescription	Nonpre-scription	Bulk	Total	Prescription	Nonpre-scription	Bulk
28341	Pharmaceutical preparations affecting neoplasms, endocrine system, and metabolic diseases, for human use.	$3,465	$3,350	$28	$87	$3,616	$3,541	$29	$46
28342	Pharmaceutical preparations acting on the central nervous system and the sense organs, for human use.	$8,097	$5,991	$2,051	$55	$7,932	$6,046	$1,828	$58
28343	Pharmaceutical preparation acting on the cardiovascular system, for human use.	$4,747	$4,560	$34	$154	$4,854	$4,680	$11	$162
28344	Pharmaceutical preparations acting on the respiratory system, for human use.	$4,998	$2,827	$2,140	$30	$4,966	$3,037	$1,890	$38
28345	Pharmaceutical preparation acting on the digestive or the genito-urinary systems, for human use.	$7,252	$5,866	$1,357	$29	$7,724	$6,446	$1,235	$43
28346	Pharmaceutical preparations acting on the skin, for human use.	$1,796	$579	$1,209	$7	$1,942	$552	$1,378	$11
28347	Vitamin, nutrient, and hemantic preparations, for human use.	$3,229	$1,164	$1,728	$337	$3,857	$1,484	$1,969	$404
28348	Pharmaceutical preparations affecting parasitic and infective diseases, for human use.	$6,561	$5,795	$665	$102	$7,165	$6,414	$608	$143
28349	Pharmaceutical preparations for veterinary use.	$1,226	$444	$710	$73	$1,151	$398	$705	$47
Total for SIC 2834		$41,371	$30,576	$9,922	$874	$43,205	$32,560	$9,652	$952
% of Total for SIC 2834		100%	74%	24%	2%	100%	75%	22%	2%

Table 3-6 (continued)

SIC Code	Product Description	1995				1996			
		Total	Prescription	Non prescription	Bulk	Total	Prescription	Non prescription	Bulk
28341	Pharmaceutical preparations affecting neoplasms, endocrine system, and metabolic diseases, for human use.	$3,526	$3,444	$57	$24	$4,021	$3,946	$40	$34
28342	Pharmaceutical preparations acting on the central nervous system and the sense organs, for human use.	$7,982	$6,039	$1,862	$81	$8,594	$6,722	$1,808	$65
28343	Pharmaceutical preparation acting on the cardiovascular system, for human use.	$5,180	$5,046	$11	$122	$5,865	$5,736	$19	$110
28344	Pharmaceutical preparations acting on the respiratory system, for human use.	$4,495	$2,832	$1,614	$48	$4,361	$2,764	$1,518	$78
28345	Pharmaceutical preparation acting on the digestive or the genito-urinary systems, for human use.	$7,433	$6,256	$1,149	$29	$7,243	$6,146	$1,060	$38
28346	Pharmaceutical preparations acting on the skin, for human use.	$1,878	$578	$1,280	$20	$1,746	$615	$1,120	$13
28347	Vitamin, nutrient, and hemantic preparations, for human use.	$4,162	$1,504	$2,236	$422	$4,558	$1,478	$2,626	$453
28348	Pharmaceutical preparations affecting parasitic and infective diseases, for human use.	$6,224	$5,462	$594	$168	$6,078	$5,438	$520	$120
28349	Pharmaceutical preparations for veterinary use.	$1,388	$684	$642	$63	$1,474	$837	$597	$40
Total for SIC 2834		$42,267	$31,845	$9,445	$977	$43,939	$33,681	$9,309	$950
% of Total for SIC 2834		100%	76%	22%	2%	100%	77%	21%	2%

Prescription: A drug product that, by federal law, is available only by prescription by a licensed physician.
Nonprescription: A drug product that is sold over the counter, whether advertised or otherwise promoted to the professions or the general public.
Bulk: Represents the value of dosage forms shipped in bulk to other plants of the same company or other companies.
Source: U.S. Department of Commerce, 1996, 1995, 1994. *Current Industrial Reports: Pharmaceutical Preparations, Except Biologicals*. MA28G(96)-1, MA28G(95)-1, MA28G(94)-1. Washington, DC: U.S.Government Printing Office.

Table 3-7

Facility, Owner Company, and Parent Company Revenues (billions of 1990 dollars)

Production Cost Category	1988		1989		1990	
	Total	Average	Total	Average	Total	Average
Facilities (n = 212)						
Revenues from sales of pharmaceutical products (domestic and international)	$13.4	$0.06	$14.6	$0.07	$17.0	$0.08
Nonpharmaceutical sales	$3.4	$0.02	$4.0	$0.02	$4.2	$0.02
Total revenues*	$16.8	$0.08	$18.6	$0.09	$21.2	$0.10
Owner Companies (n = 157)						
Revenues from sales of pharmaceutical products (domestic and international)	$42.6	$0.3	$44.4	$0.3	$48.8	$0.3
Nonpharmaceutical sales	$42.6	$0.3	$48.2	$0.3	$48.9	$0.3
Total revenues*	$86.9	$0.6	$94.4	$0.6	$99.8	$0.6
Parent Companies (n = 68)						
Revenues from sales of pharmaceutical products (domestic and international)	$73.3	$1.1	$80.6	$1.2	$80.7	$1.2
Nonpharmaceutical sales	$213.7	$3.1	$215.1	$3.2	$218.7	$3.2
Total revenues*	$292.3	$4.3	$295.7	$4.3	$305.2	$4.5

*Pharmaceutical revenues and nonpharmaceutical revenues might not add to total revenues because of inconsistencies in survey reporting.
Source: Section 308 Pharmaceutical Survey.

Table 3-8

Distribution of Surveyed Facilities by Value of Shipments: 1990

Value of Shipments (Millions of Dollars)	Pharmaceutical Shipments		Nonpharmaceutical Shipments		Total Shipments	
	Number of Facilities	Percentage of Facilities	Number of Facilities	Percentage of Facilities	Number of Facilities	Percentage of Facilities
0	3	1%	132	62%	3	1%
>0-1	2	1%	15	7%	11	5%
>1-5	29	14%	9	4%	17	8%
>5-25	64	30%	25	12%	65	31%
>25-100	50	24%	21	10%	62	29%
>100-250	31	15%	8	4%	36	17%
>250	15	7%	2	1%	18	8%

Source: Section 308 Pharmaceutical Survey.

surveyed.[22] As shown in Table 3-7, these 212 facilities generated $21.2 billion in revenues in 1990, an average of approximately $100 million per facility. Pharmaceutical revenues accounted for over 80 percent of total revenues. Table 3-8 shows the distribution of facilities by pharmaceutical, nonpharmaceutical, and total revenues. Over 62 percent of the facilities reported having no nonpharmaceutical revenues at all.

Company-level pharmaceutical revenues in the sample totaled $42.6 billion in 1988, $44.4 billion in 1989, and $48.8 billion in 1990 (see Table 3-7).[23] Total company-level revenues in the sample (including nonpharmaceutical revenues) totaled $86.9 billion in 1988, $94.4 billion in 1989, and $99.8 billion in 1990. Average revenues remained essentially flat over the period at approximately $600 million per owner company. Owner companies in the sample generated close to 50 percent of total revenues from pharmaceuticals.[24]

Parent company pharmaceutical revenues in the sample totaled $73.3 billion in 1988, $80.6 billion in 1989, and $80.7 billion in 1990. Total revenues reported by parent companies included in the survey came to $292.3 billion in 1988, $295.7 billion in 1989, and $305.2 billion in 1990. In 1990, parent companies generated 27 percent of their revenues from the sale of pharmaceuticals.

Table 3-9 shows the distribution of surveyed owner companies and parent companies by total revenues. Approximately one-third of the owner companies reported revenues of less than $25 million, one-third reported between $25 and $200 million, 21 percent between $200 million and $1 billion, and the remaining 13 percent over $1 billion. Approximately one-third of the parent companies sampled reported revenues of less than $250 million, 16 percent between $250 million and $1 billion, 35 percent between $1 billion and $10 billion, and 16 percent over $10 billion.

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[22] It has not been determined why so many of the surveyed facilities failed to report revenues for all 3 years surveyed. This lack of reporting may be caused by change of ownership.

[23] Approximately 42 percent of the owner companies surveyed derive 100 percent of their revenues from pharmaceutical sales.

[24] Company-level revenues from the survey and U.S. Department of Commerce are not directly compared because foreign revenues are treated differently.

Table 3-9

Number of Surveyed Owner Companies and Parent Companies by Total Revenues: 1990 (millions of 1990 dollars)

Owner Companies		Parent Companies	
Total Revenues	**Number of Companies**	**Total Revenues**	**Number of Companies**
$0-$25	50	$0-$250	23
≥$25-$200	50	≥$250-$1,000	11
≥$200-$1,000	33	≥$1,000-$10,000	24
≥$1,000	24	≥$10,000	10

Source: Section 308 Pharmaceutical Survey.

3.2.3 Production Costs

This section presents R&D, manufacturing, and marketing cost data for the pharmaceutical industry.[25] Production costs are broken down in this way because these cost categories play very different roles in industry performance—and in individual companies' decisions to engage in these activities. (Recall that the pharmaceutical industry includes many companies that focus on one or two of these areas, while many large companies engage in all three.) R&D and promotional costs, in particular, play a unique and critical role in realizing long-term gains in the pharmaceutical industry.

3.2.3.1 Research and Development

The cost of researching, developing, and obtaining market approval for a new drug is a significant component of total production costs. According to the U.S. Department of Commerce, the pharmaceutical industry spent approximately $11 billion in 1992 on R&D.[26] The industry spent $12.6 billion—14.5 percent more—in 1993.[27] These expenditures amounted to more than 16 percent of sales, one of the highest investment levels in any U.S. industry, and double the level invested in other high-technology industries. PhRMA estimates that its members spent about $13 billion to $14 billion on R&D in 1994 and 1995 and projects spending $15.8 billion in 1996—an all-time high representing about 19 percent of sales.[28] FDA estimates that 9 percent of all U.S. industrial R&D is in pharmaceuticals.[29]

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[25] Unless otherwise noted, all cost data are presented in 1990 dollars.

[26] U.S. Department of Commerce, 1993. *Op. cit.*

[27] U.S. Department of Commerce, 1994. *Op. cit.*

[28] PhRMA, 1996. R&D as a Percent of U.S. Sales, *Ethical Pharmaceuticals, PhRMA Member Companies, 1970-1996.* Document Number 5070. (Also Document Numbers 8013, 8019, and 8021.) Pharmaceutical Research and Manufacturers of America.

[29] FDA, 1990. U.S. Food and Drug Administration, Office of Drug Evaluation. *Overview of the Competitiveness of the U.S. Pharmaceutical Industry*. Presentation to the Council on Competitiveness. Rockville, MD: U.S. FDA.

Table 3-10

Cost of Pharmaceutical Production in Surveyed Population
(billions of 1990 dollars)

Production Cost Category	1988		1989		1990	
	Total	Average	Total	Average	Total	Average
Facility Level (n = 204)						
Cost of pharmaceutical products	$6.1	$0.03	$6.3	$0.03	$6.4	$0.03
Cost of nonpharmaceutical products	$1.3	$0.01	$3.1	$0.02	$3.2	$0.02
Total cost of goods sold	$7.4	$0.04	$9.4	$0.05	$9.6	$0.05
Company Level (n = 98)						
Cost of pharmaceutical products	$19.7	$0.2	$20.0	$0.2	$21.3	$0.2
Cost of nonpharmaceutical products	$39.0	$0.4	$43.0	$0.4	$42.5	$0.4
Total cost of goods sold	$58.7	$0.6	$63.0	$0.6	$63.8	$0.7
Total operating cost (not including cost of goods)	$35.6	$0.4	$40.0	$0.4	$40.0	$0.4
Research and development expenditures	$9.8	$0.1	$10.3	$0.1	$10.9	$0.1
Parent Company Level (n = 63)						
Cost of pharmaceutical products	$25.3	$0.4	$27.6	$0.4	$29.7	$0.5
Cost of nonpharmaceutical products	$123.8	$2.0	$134.8	$2.1	$145.6	$2.3
Total cost of goods sold	$149.1	$2.4	$162.4	$2.6	$177.3	$2.8
Total operating cost (not including cost of goods)	$67.7	$1.1	$77.1	$1.2	$86.0	$1.4
Research and development expenditures	$14.3	$0.2	$15.6	$0.2	$17.4	$0.3

Source: Section 308 Pharmaceutical Survey.

Data on R&D and other production costs in the pharmaceutical industry are also available from the Section 308 Pharmaceutical Survey. Table 3-10 presents cost data at the facility, owner company, and parent company levels for the sampled entities. Costs are broken down into the cost of pharmaceutical products and nonpharmaceutical products (including the cost of labor, capital, materials, and overhead), total operating expenditures (e.g., energy, depreciation), and R&D. In 1990, R&D costs among the surveyed firms amounted to $10.9 billion at the company level (an average of $100 million per owner company) and $17.4 billion at the parent company level (an average of $300 million). R&D costs averaged approximately 20 percent of the cost of goods sold over the 3 years reported in both owner and parent companies. The reported expenditures include nonpharmaceutical R&D expenditures as well. R&D cost data were not available at the facility level.

The research required to discover and develop NMEs is central to pharmaceutical R&D, because manufacturers of generics and chemically similar products build on the knowledge produced in the course of developing NMEs. NMEs are discovered either through screening existing compounds or designing new molecules. Once discovered, NMEs undergo rigorous preclinical testing in laboratories and animals and then clinical testing in humans to establish the compounds' safety and effectiveness (see Section 3.1.2.1). Further clinical studies might be conducted following market approval.

The primary component of R&D cost is labor. Pharmaceutical R&D draws on the expertise of a diverse array of biological, chemical, and physical scientists to discover NMEs with potential therapeutic benefits. Also of importance in pharmaceutical R&D is the opportunity cost of capital, which can be quite high given the risk and time involved. By some estimates, for every 9,999 compounds on which research is conducted, only one drug product is introduced to the market. A typical pharmaceutical company will require 9 to 12 years to bring an NME to market.[30] PhRMA's estimates are slightly different (1 of 5,000 compounds reach the market, with an average "lab to medicine chest" time of 12 to 15 years), but also indicate the magnitude of the risk and time involved in R&D.[31]

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[30] U.S. Congress, Office of Technology Assessment (OTA), 1993. *Pharmaceutical R&D: Costs, Risks, and Rewards.* Washington, DC: U.S. Government Printing Office.

[31] Moore, 1996. *Op. cit.*

Tuft's Center for the Study of Drug Research, a research institute specializing in the pharmaceutical industry, estimated that it costs an average of $231 million ($1990) to bring an NME to market. Approximately half of this total is the cost of capital.[32] In a study of the costs of pharmaceutical R&D, the Office of Technology Assessment (OTA) estimated that the aftertax R&D cash outlay for each NME that reached the market in the 1980s was about $65 million ($1990). The full aftertax cost of these outlays, compounded over 12 years to the day of market approval, was approximately $194 million ($1990).[33] More recently, an industry analyst cited estimates of $200 million to $500 million.[34] These cost estimates include R&D expenditures for unsuccessful as well as successful product development efforts, according to OTA. Moreover, an industry analyst noted that even of those compounds that do make it to market, only two or three out of every ten are profitable enough to recover their R&D costs; thus, high-sales drugs must pay for their own R&D costs, the R&D costs of lower sales drugs, and the R&D costs of drugs that never make it to market.[35]

OTA points out that the cost of pharmaceutical R&D is highly sensitive to changes in science and technology and in the regulatory environment, both of which are continuously evolving. Consequently, OTA warns that one cannot predict future R&D costs from current estimates, which are based on R&D costs for drugs that went into development more than 10 years ago. Nevertheless, some evidence, including the industry data noted above, suggests that pharmaceutical R&D is becoming more expensive over time as firms devote greater resources to hiring scientists, investing in new technology, and submitting their products to more extensive preclinical and clinical testing.

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[32] DiMasi, J.A., Hansen, R.W., Grabowski, H.G., et al., 1991. The Cost of Innovation in the Pharmaceutical Industry. *Journal of Health Economics* 10:107-142.

[33] OTA, 1993. *Op. cit.*

[34] Moore, 1996. *Op. cit.*

[35] *Ibid.*

3.2.3.2 Manufacturing Costs

Data on manufacturing (product and operating) costs from the Section 308 Pharmaceutical Survey are presented in Table 3-10. Product and operating costs rose from 1988 to 1990 in real terms ($1990) at the facility, owner company, and parent company levels. Excluding R&D expenditures, the total cost of production rose from $7.4 billion to $9.6 billion at the facility level, from $58.7 billion to $63.8 billion at the owner company level, and from $149.1 billion to $177.3 billion at the parent company level. The cost of pharmaceutical production as a percentage of the total cost of goods sold was approximately 67 percent at the facility level, 33 percent at the owner company level, and 17 percent at the parent company level in 1990.

3.2.3.3 Marketing

Promotional expenditures amount to approximately 22 percent of the industry's revenues.[36] Promotional expenditures tend to decline as a percentage of total sales over the life of the drug. For example, OTA estimates that in the second year following market approval, promotional expenditures account for 50 percent of sales. By the product's tenth year, however, promotional expenditures will have declined to only 6.5 percent of sales.[37]

Many view these high promotional expenditures as evidence that the industry does not compete on the basis of price and instead devotes excessive resources to product differentiation through advertising. Others contend that price should not be the only (or even the main) basis for competition in the therapeutic arena—that because good patient care dictates matching patient characteristics with drug features, promotional expenditures serve a useful and appropriate function in educating physicians about proper drug uses (i.e., through differentiating products by clinical as well as cost features). In addition, these analysts argue, high promotional expenditures help increase competition by allowing new competitors to enter specific drug markets. These issues are discussed further in Sections 3.3.1 and 3.3.3.

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[36] Day, Kathleen, 1993. Putting a Price on a Pill: Drug Firms Weigh New Intangibles in Setting Costs. *The Washington Post.* March 21,1993.

[37] OTA, 1993. *Op. cit.*

3.2.4 International Trade

3.2.4.1 U.S. Department of Commerce Data

With U.S. manufacturers accounting for nearly half of the major pharmaceuticals marketed worldwide, the U.S. pharmaceutical industry has consistently maintained a positive balance of trade in international markets. In 1991, the industry's trade surplus totaled $919 million; exports totaled $5.7 billion compared to $4.8 billion in imports. The U.S. Department of Commerce estimates that the industry's trade surplus declined to $755 million in 1992, rose to $1,059 million in 1993, and declined again to $526 million in 1994 due to increasing international competition, price controls, illegal use of patents and copyrights, and foreign regulations on marketing and R&D.

Just over 48 percent of the industry's exports were to the European Community in 1992. With $963 million in U.S. drug purchases, Japan represented the greatest single-country importer of U.S. pharmaceuticals. On the import side, the United States purchased $932 million in pharmaceuticals from the United Kingdom. Figure 3-8 shows U.S. pharmaceutical exports and imports for 1992.

The United States holds a dominant position in many international pharmaceutical markets. In Europe, for example, U.S. pharmaceutical companies account for 25 percent of total pharmaceutical sales. The United States also has a strong presence in Japan, with 10 percent of the market. Worldwide (including the United States), U.S. companies account for 33 percent of total pharmaceutical sales.[38] In important markets such as the United States, the United Kingdom, and France, U.S. companies have introduced the largest percentage of new drugs. Even in Japan, the United States is second only to Japan in new drug introductions.

As in many U.S. industries, foreign investment in U.S. pharmaceutical companies subsided in 1992 after peaking in the late 1980s. In 1990, foreign investment in U.S. pharmaceutical companies totaled $10 billion, while U.S. investment in foreign pharmaceutical companies totaled $10.6 billion.

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[38] FDA, 1990. *Op. cit.*

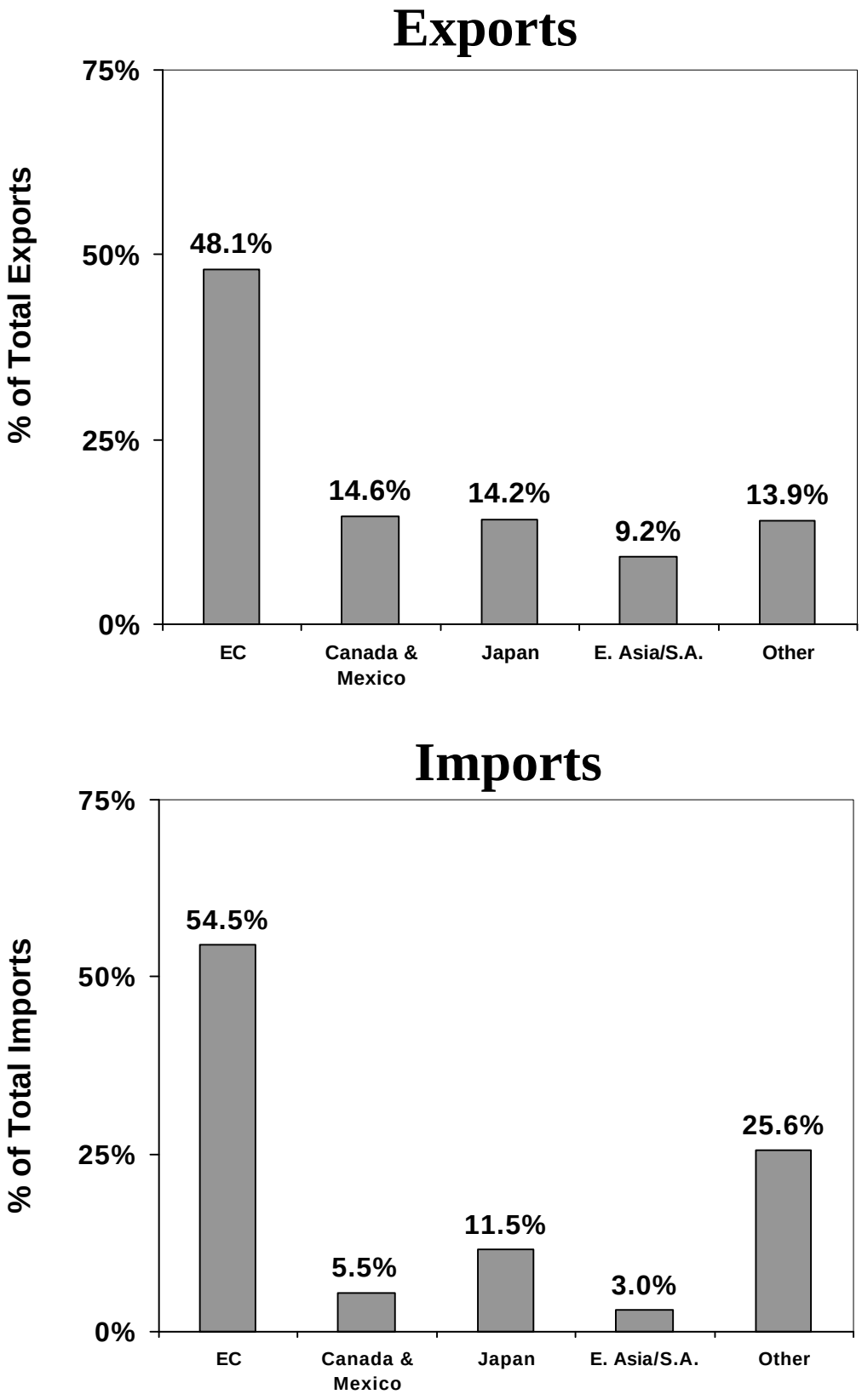

Figure 3-8. U.S. pharmaceutical exports and imports: 1992.

Source: U.S. Department of Commerce. 1994. *U.S. Industrial Outlook: 1994.* Washington, DC: U.S. Government Printing Office.

Despite the obstacles noted above, the U.S. Department of Commerce expects the United States to maintain a strong position in international markets over the next decade. Nearly 33 percent of worldwide pharmaceutical R&D is conducted by U.S. firms, thus providing the United States with a competitive edge for developing new drug products. The North American Free Trade Agreement (NAFTA), the advent of an economically unified Europe, and the increasing recognition of U.S. patent laws in China, Mexico, and Latin America, all suggest continued strength in international markets for the U.S. pharmaceutical industry. Greater political stability in the former Soviet Union and other Eastern Block countries also will create new trading opportunities for the U.S. pharmaceutical industry.

3.2.4.2 Survey Data

According to the Section 308 Survey data, international sales account for a significant proportion of the total revenues of surveyed facilities, owner companies, and parent companies. This finding is not surprising given the multinational character of the pharmaceutical industry (nearly 50 percent of the parent companies of surveyed facilities are headquartered in foreign countries). At the company level, international sales accounted for over 25 percent of all pharmaceutical revenues generated in 1990. Nearly 50 percent of all pharmaceutical sales made by parent companies in 1990 were to foreign countries. International sales are an important component of overall pharmaceutical sales at the facility level as well. Table 3-11 presents the distribution of surveyed facilities by percentage of pharmaceutical shipments accounted for by international sales. Although a substantial number (44 percent) of the surveyed facilities reported no international pharmaceutical sales, over 20 percent of the facilities reported receiving more than 10 percent of their pharmaceutical revenues from international sales in 1990. The mean pharmaceutical export rate for sample facilities was 8.8 percent in 1990.

3.2.5 Financial Conditions

The Section 308 Survey collected data on company costs, revenues, liabilities, earnings, and other financial statistics. These data allow key financial ratios to be calculated. The ratios are measures of a company's ability to meet short- and long-term obligations and to generate a sufficient return on investments. This section presents baseline data on two financial ratios: (1) rate of return on assets (ROA) and interest

Table 3-11

Number of Facilities by Percentage of Pharmaceutical Shipments Exported

Percentage of Pharmaceutical Shipments Exported	1989		1990	
	Number	%	Number	%
0%	82	46.9%	77	44.0%
>0%-2.5%	33	18.9%	36	20.6%
>2.5-5%	13	7.4%	13	7.4%
>5%-10%	11	6.3%	10	5.7%
>10%	36	20.6%	39	22.3%

Note: Only 175 facilities reported export data.

Source: Section 308 Pharmaceutical Survey.

coverage ratio (ICR), or times interest earned ratio. These ratios are similar to ratios used as part of the analysis in Section Six. They are presented here because these ratios can be easily compared to ratios developed for the pharmaceutical industry as a whole, and thus provide a comparison of the subgroup of firms affected by effluent guidelines to the larger pharmaceutical industry. In Section Six, similar ratios are used in an equation that allows the affected firms to be compared to the entire manufacturing sector, for both publicly and privately held firms.

The two financial ratios investigated in this profile are calculated at the owner company level only, where firm impacts are most direct and substantial. The ratios are also compared with industry benchmarks obtained from Dun & Bradstreet Information Services and Robert Morris Associates.

To attract the financing for a wastewater treatment system, a firm must demonstrate or project financial strength both before and after the regulation-induced investment. Financial strength is often assessed on the basis of whether a firm can incur debt associated with a capital investment while continuing to generate a return on investment that will attract further investment. Thus, measures of liquidity, debt levels, and profitability are critical to the analysis of financial strength.

The two ratios investigated here provide some evidence to potential creditors and investors on the affected firms relative to trends in the industry, although these ratios can be less helpful to analysts when one ratio looks “bad,” and the other ratio looks “good.” The analysis undertaken in Section Six solves this problem by combining a number of different ratios (which include return ratios and debt ratios) into an equation known as Altman’s Z, which gives varying weights to the different ratios on the basis of their ability to predict bankruptcy.

The sections below define the two ratios presented here (to provide a general comparison to the financial health of the affected firms relative to other firms in the industry) and discuss their value for this profile. Additionally, the discussion reviews the overall profitability of the industry, which helps to provide background for the remainder of the financial analysis.

3.2.5.1 Return on Assets

A firm's financial performance determines the willingness of creditors and investors to provide the capital necessary to sustain or expand operations. If performance is poor, investors will not provide capital or will seek higher returns in the form of higher interest rates on debt or higher returns on equity to compensate for above-average levels of risks. The higher cost of capital might in turn limit the ability of a given company to invest in improved wastewater treatment.

One aspect of financial performance can be measured in terms of the return on assets (ROA). ROA is computed as the ratio of net income to assets:

$$ROA = \frac{Net\ Income}{Total\ Assets}$$

ROA is a measure of profitability of a firm's capital assets, independent of the effects of taxes and financial structure. It is perhaps the most comprehensive measure of a firm's financial performance. ROA provides information about the quality of a firm's management, the competitive position of a firm within its industry, and, on an aggregate level, the economic condition of an industry overall. In addition, ROA incorporates information about a firm's operating margin and asset management capability: the ratio of net income to sales (operating margin), multiplied by the ratio of sales to assets (asset turnover), equals ROA. If a firm cannot sustain a competitive ROA, it will probably have difficulty financing new investments. This is true regardless of whether the financing is obtained through debt or equity financing.

Table 3-12 presents baseline ROA data for companies included in the survey sample. The ratio data are presented by quartile (i.e., with values given that denote the ratios for lowest 25 percent of firms, the median, and the highest 25 percent of firms) for firms grouped by annual revenues. The mean and standard deviation for each group of firms also are presented.

The return on assets over the years 1988 to 1990 varied from a first quartile of approximately -3 percent to an upper quartile of 10 percent for the smallest size class of firms (those with $25 million or less in annual revenues), to between 4 and 9 percent for the largest firms (those with over $1 billion in revenues). The data indicate that the lower quartile of firms in the smallest size class, on average, generated negative net income between 1988 and 1990. These firms appear to be the most vulnerable financially.

Table 3-12

Baseline Return on Assets (ROA) and Interest Coverage (ICR) Ratios, by Annual Revenues

Annual Revenues (Millions)	Number of Observations	Mean	Lower Quartile	Median	Upper Quartile
ROA					
0-25	60	-2%	-3%	5%	10%
26-200	55	5%	1%	5%	12%
201-1,000	33	15%	2%	7%	26%
>1,000	26	7%	4%	6%	9%
ICR					
0-25	60	Infinity	-1%	578%	51,267%
26-200	55	Infinity	201%	464%	8,470%
201-1,000	33	Infinity	272%	2,043%	Infinity
>1,000	26	1,111%	372%	677%	1,130%

Source: Section 308 Pharmaceutical Survey.

Long-term performance at this level would threaten these firms' ability to stay in operation. All other ROA values given in the table are positive.

Table 3-13 presents industry ROA ratios reported by Dun & Bradstreet for each SIC of the pharmaceutical industry. As can be seen, the results are more or less consistent with those drawn from the survey sample. Dun & Bradstreet's results reflect data for 266 companies overall. It should be noted that differences in the organization of data makes the comparison of ratio results only approximate. Comparing updated Dun & Bradstreet results with the 1990 data reveals an increase in ROA in all quartiles in the SIC 2833 pharmaceutical industry sector, suggesting that the financial condition of SIC 2833 pharmaceutical companies represented in the Dun & Bradstreet data strengthened in the early 1990s. The ROA data for other industry sectors are mixed, showing modest increases or decreases depending on the sector and quartile.

3.2.5.2 Interest Coverage Ratio

The second general area of concern to creditors and investors is the extent to which the firm can be expected to manage its financial burdens without risk of financial failure. In particular, if a firm's operating cash flow does not comfortably exceed its contractual payment obligations (e.g., interest and lease obligations), the firm is vulnerable to a decline in profits or an increase in costs because in either case its ability to continue meeting interest obligations would be in jeopardy. Either scenario may (1) sharply reduce or eliminate returns to equity owners of the firms, and/or (2) prevent the firm from meeting its contractual obligations.

The ability to manage financial commitments is expressed as the ratio of earnings before interest and taxes (EBIT) to interest obligations, or the interest coverage ratio (ICR):

$$ICR = \frac{EBIT}{Interest}$$

A low ICR indicates vulnerability of the firm to financial failure and the potential for difficulty in obtaining financing for wastewater treatment capital investments.

Table 3-13

Comparison of Sample Ratios with Published Industry Averages

Source	Number of Observations	Quartile		
		Lower	Median	Upper
ROA				
Survey Sample (1988-1990 average)	174*	-3% to 4%	5% to 7%	9% to 26%
Dun & Bradstreet Information Services (1990)				
SIC 2833	34	-2%	2%	11%
SIC 2834	167	3%	10%	21%
SIC 2835	29	NA	4%	7%
SIC 2836	34	0%	4%	10%
Dun & Bradstreet Information Services (1994)				
SIC 2833	44	4%	14%	22%
SIC 2834	202	3%	8%	17%
SIC 2835	36	-1%	1%	8%
SIC 2836	40	-4%	3%	11%
ICR				
Survey Sample (1988-1990 average)	174*	-1% to 372%	464% to 2,043%	1,130% to Infinity
Robert Morris Associates (1991-1992)				
SIC 2833	113	180%	440%	1,110%
Robert Morris Associates (1993-1994)				
SIC 2833	126	230%	710%	2,910%

*Out of 177 firms, only 174 responded with data for computing ROA and ICR.

Sources: Section 308 Pharmaceutical Survey data; Robert Morris Associates, 1994, 1992. *Annual Statement Studies*. Philadelphia, PA: Robert Morris Associates; Dun & Bradstreet Information Services, 1995, 1993. *Industry Norms and Key Business Ratios: Desk-Top Edition*. New York: Dun & Bradstreet.

As shown in Table 3-12, the interest coverage ratios vary from approximately -1 percent to 51,267 percent for the smallest firms to 372 percent to 1,130 percent for the largest firms in the Section 308 sample of firms. A number of firms reported no or negative interest burdens over the specified time period. These firms were assigned ICRs of infinity. Only the lowest quartile of companies in the smallest size class showed negative interest coverage ratios.

Robert Morris Associates reported data on the interest coverage ratios for 113 firms. As for ROA, these data are approximately consistent with those reported by the survey sample (see Table 3-13). The median value in the Robert Morris sample is 440 percent. Median values for the survey sample by size class ranged from 464 percent to 2,043 percent. Robert Morris Associates published updated ICR data in 1994.[39] Like Dun & Bradstreet's ROA figures for the pharmaceutical industry, these new ICR figures are higher than the 1991-1992 figures, again suggesting that the financial condition of pharmaceutical companies has strengthened.

3.2.5.3 Overview of Profitability in the Pharmaceutical Industry

This section presents additional evidence on profitability in the pharmaceutical industry. If the pharmaceutical industry were found to be relatively unprofitable overall, investment levels in the industry would be declining and industry benchmarks might underestimate the extent of vulnerability among industry firms. This is, however, not the case as can be seen in the discussion below and in the analysis of profit margins in Section Eight of this EA.

Profitability in the pharmaceutical industry has been extensively studied, and an OTA research report, *Pharmaceutical R&D: Costs, Risks and Rewards,* summarizes this work.[40] OTA compared the pharmaceutical industry's rate of return with that of other industries. OTA also considered whether the higher rates of return in the pharmaceutical industry were caused by a higher cost of capital in the industry. Elements of the OTA research are summarized here.

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[39] Robert Morris Associates, 1994. *Annual Statement Studies.* Philadelphia, PA: Robert Morris Associates.

[40] OTA, 1993. *Op. cit*

OTA compiled recent literature on the profitability and internal rates of return (IRR) for the pharmaceutical industry. The IRR is the interest rate at which the net present value of all cash flows into and out of the company equals zero. It provides a generally reliable method of calculating the return on investments. OTA identified a number of studies conducted between 1975 and 1991 that measured the profitability of the industry, including three studies that compared the pharmaceutical industry to others. These studies were designed to improve on the measurements possible with publicly available reports of industry profits. Accounting measures of profitability can be flawed because:

- Accounting standards require firms to record R&D, advertising, and promotion outlays as current expenditures, whereas they are generally investments with a future return. The value of the "intangible assets" represented by these expenditures is too uncertain for use in accounting statements but, nevertheless, represents assets that should be factored in.

- Financial statements report income and expenses as they are accrued and not necessarily as they are realized, which can distort the timing of revenues and investments and misrepresent the rate of return.

- Even if the other distortions are corrected, the accounting rate of return could still depart from the IRR because accounting profits do not adjust properly for the time profile of cash flows from various investments and are further distorted by growth or decline in investment over time.[40]

The studies identified by OTA used various techniques to develop more accurate estimates of the rate of return for the companies studied, such as incorporating information about the timing of investments in R&D, correcting for the effect of inflation, incorporating depreciation rates for investments in R&D and advertising, and other changes. The various studies produced estimates of the IRR.

Three studies compared the corrected pharmaceutical industry IRR estimates with similarly adjusted profit figures for other industries. The study results should be interpreted cautiously because they covered very small samples of companies. Further, the studies tended to focus on larger (and presumably more successful) firms; large pharmaceutical firms tend to be innovative, vertically integrated companies with high costs and relatively high profits, while smaller firms (e.g., many of those concentrating on the production of generics) tend to have competition and profit profiles that more closely resemble those of other

[40] OTA, 1993. *Op. cit.*

manufacturing industries. The studies found the adjusted rate of return for the pharmaceutical industry to be consistently higher than that in the other industries examined.

Table 3-14 summarizes the elements of the most recent of the studies reviewed by OTA, a study by Megan and Mueller of 10 pharmaceutical firms between 1975 and 1988. Megan and Mueller compared the IRR for the pharmaceutical industry with that of other industries that have similarly large investments in R&D and advertising, including the toy, distilled beverages, and cosmetics industries. These authors used various assumptions about the depreciation of R&D and advertising to measure the true profitability impact of these investments. This study found that 10 pharmaceutical firms had an IRR of 12.15 percent. The other industries, with similarly adjusted depreciation estimates, produced rates of return of 6.6 percent (toys), 11.44 percent (distilled beverages), and 11.5 percent (cosmetics).

OTA also commissioned its own report on the relative level of pharmaceutical industry profits. This study, authored by Baber and Sok-Hyon, used a recently developed technique for converting accounting data into an IRR estimate. This study compared rates of return for 54 research-intensive pharmaceutical firms with samples of companies in other industries. The authors found that the pharmaceutical industry had IRRs that were consistently 2 to 3 percentage points higher, under various alternative calculation methodologies, than those for nonpharmaceutical companies.

The question remains whether the observed differences in IRR resulted from differences in the cost of capital. If pharmaceutical investments are riskier, investors would require higher IRR and the cost of capital for the industry would be higher. OTA estimated the average cost of capital for the industry and for two control groups. OTA found that the pharmaceutical industry's cost of capital was slightly higher than that for one group of control firms and lower than that for another group. OTA recognized the potential errors and biases in its measurement techniques, but nevertheless concluded that the higher rates of return found for the pharmaceutical industry could not be explained by differences in the relative costs of capital.

Overall, the profitability of the pharmaceutical industry appears to be above average among U.S. industries. This suggests that the overall baseline viability of the industry is equivalent to, if not better than, that of other industries. This finding is also supported in Section Eight of the EA, in which the median profit

Table 3-14

Summary of Megan and Mueller Pharmaceutical Industry Profits Study

Study Description	Study Characteristics	Comment
Pharmaceutical industry sample (year of data)	10 major firms (1975 to 1988).	
Other industries sample	Selected firms in advertising or R&D-intensive industries; 6 firms in toy industry; 4 in distilled beverage firms; 9 in cosmetic firms.	Selected firms with similar large investments in R&D and advertising.
R&D capitalization assumptions	R&D depreciation rates estimated for each firm by regressing sales on lagged R&D. Maximum 8-year life for investment.	Capitalization rate assumptions are necessary to improve accuracy of rate of return estimates over normal accounting measures.
Advertising capitalization assumptions	Same depreciation estimation technique as for R&D with a maximum 4-year life for investment.	Capitalization rate assumptions are necessary to improve the accuracy of rate of return estimates over normal accounting measures.
Rate-of-return estimates—pharmaceutical industry	12.15%	
Rate-of-return estimates—other firms	Toy industry - 6.66% Distilled beverages - 11.44% Cosmetics - 11.51%	Other industries showed lower rates of return, using consistent adjustments to the accounting data.

Source: U.S. Congress, OTA. 1993. *Pharmaceutical R&D: Costs, Risks, and Rewards*. Washington, DC: U.S. Government Printing Office.

margin of the affected firms (posttax EBIT/revenues) is shown to be substantially higher than U.S. industry averages (7.4 percent vs. 4.9 percent).[41]

3.3 INDUSTRY STRUCTURE AND THE PHARMACEUTICAL MARKET

Information concerning market structure, the demand for pharmaceuticals, and pricing behavior provides much of the basis for reaching conclusions about the industry's ability to "pass through" additional regulatory costs via higher drug prices and thereby predicting which entities bear what portions of regulatory impacts. The first section of the following discussion (Section 3.3.1) examines the pharmaceutical industry's market structure as defined by barriers to entry, industry concentration ratios, and vertical integration patterns. Subsequent sections examine the characteristics of pharmaceutical demand (Section 3.3.2) and market conduct and performance (Section 3.3.3). Section 3.3.4 presents conclusions about the likelihood that manufacturers can pass through regulatory costs to consumers of pharmaceuticals.

3.3.1 Market Structure

The more barriers to entry that exist in a given market, the more likely it is that monopolistic or oligopolistic conditions will prevail in that market. Such conditions allow firms greater latitude in setting prices and hence the ability to pass regulatory costs along to consumers. Barriers to entry and concomitant factors of concentration and vertical integration are discussed in the following sections.

3.3.1.1 Barriers to Entry

Critics of the pharmaceutical industry often blame barriers to entry (i.e., economic, social, and regulatory factors that prevent or discourage new firms from entering a given market) for limiting competition in the pharmaceutical industry and thereby creating inefficiencies in the supply of a socially desirable product.

[41] Section 308 Pharmaceutical Survey and Johnston, Daniel, 1992. *Oil Company: Financial Analysis in Nontechnical Language*. Tulsa, Oklahoma: PennWell Books.

High Cost of Pharmaceutical R&D

Major barriers to entry are the high cost of pharmaceutical R&D, the cost of preparing FDA applications,[42] and the length (and thus cost) of the R&D and regulatory review process, especially for innovative companies wishing to enter the new drug market; the cost (and process length) of R&D for generic and OTC drug licensing and manufacturing are lower, although still significant. Many established firms with drugs already on the market rely heavily on profits from sales of their existing drugs (as well as outside investors) to fund more R&D to create a "pipeline" of products that, when approved, will then fund more R&D. Without a pre-existing profit stream and capital resources, new firms must attract investors who can tolerate long-term, high-risk investments. Some investors are more inclined to invest in established firms that have demonstrated that they can bring a drug to market, recover R&D expenditures, and produce reasonable returns on investment capital. Some investors also might be wary of new firms that have not demonstrated that they can clear FDA regulatory hurdles, although many new firms overcome this issue by hiring regulatory affairs professionals from established firms or by contracting with outside companies specializing in handling pharmaceutical regulatory matters.

Nevertheless, many investors, anticipating large profits if a new drug is successful, are willing to invest substantial sums in new pharmaceutical firms over a period of a decade or more. Indeed, this factor accounts for the rapid proliferation of biotechnology firms over the past two decades, when advances in genetics and recombinant DNA technologies have made possible the development of recombinant DNA drugs and other gene/immunological products of potential value in treating a wide range of diseases, such as cancer, acquired immune deficiency syndrome (AIDS), Lou Gehrig's disease, asthma, diabetes, heart disease, multiple sclerosis, rheumatoid arthritis, Lyme disease, stroke, and viral infections, among others. Many biotechnology firms started in the 1970s and 1980s by scientists from established companies, academia, or research institutes have been fully funded by investors for more than a decade. Only now are some of these firms beginning to produce marketable products, yet most firms are still largely supported by investors. Analysts, however, expect a significant number of biotechnology products to come to market over the next several years and beyond, during which time investors hope to more than recoup their investments.

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[42] As noted earlier, drug sponsors must now pay FDA to review their applications, further increasing the cost of the R&D and the regulatory review process.

Recently, publication of disappointing results for a few biotechnology drugs in early clinical trials has dampened venture capitalists' enthusiasm for biotechnology companies. As a result, some companies have developed strategic partnerships or other deals with established innovative pharmaceutical companies that have money, manufacturing capacity, and sales/distribution avenues but a shortage of innovative products. Such partnerships are viewed as benefiting both parties—providing a reliable source of capital for one, and a new source of potentially highly profitable products for the other. In the new climate of cost and time pressure, biotechnology companies are expected to move more quickly and efficiently in the 1990s and beyond, but are still expected to flourish with the help of some combination of venture capital investment and pharmaceutical corporate partnerships.

Patents

By law, patented drugs in the United States enjoy ostensible protection from bioequivalent drugs for a period of 17 years.[43] This protection gives the drug manufacturer a monopoly over its particular product for the life of the patent. Several factors, however, act to reduce the effective patent life of drugs. The greatest threat to the effective patent protection for a drug is the delay between patent issuance and FDA approval, which can be as much as 10 years. Drug companies obtain patents during the R&D phase, and many years can elapse before the company can take advantage of its monopoly power. OTA estimates that the effective patent life (i.e., the time between drug approval and patent expiration) on new drugs averages 11 years.[44]

Although patents give manufacturers a monopoly over new drugs for the life of the patent, preventing new (or established) firms from entering the market for those specific drugs, patents do not provide protection from competition because competitors may and often do offer other drugs with similar therapeutic benefits. As illustrated in the example in Section 3.1.2, a new drug can face stiff competition from other branded, patented drugs and generic drugs in the same therapeutic class. In some of the largest therapeutic classes (e.g., anti-infectives and antihypertensives), competition is intense.

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[43] OTA, 1993. *Op. cit.*

[44] *Ibid.*

Once patents expire, manufacturers of bioequivalent, or generic, drugs can enter the market. Evidence suggests that over the past decade, introduction of generic versions of branded products is becoming more common. Today, nearly 34 percent of all prescription drug orders are filled by generics rather than branded, or "pioneer" drugs, an 11 percent increase since 1986. As noted earlier, the passage of the 1984 Price Act made it easier for generics to gain market approval from FDA, and both public and private insurers have become more adamant about the use of less expensive generics.

High Promotional Expenditures

High promotional expenditures in the pharmaceutical industry also can serve as a barrier to entry. Traditionally, the economic literature has viewed high promotional expenses as an indication of an imperfect competitive environment. In a market characterized by oligopoly (i.e., the domination of a given market by a small number of firms), firms will use advertising rather than price competition to differentiate products.

As noted earlier, however, proponents of pharmaceutical advertising argue that such advertising plays a crucial role in a market in which both clinical and cost issues are central to prescribing and purchasing decisions. In this setting, advertising serves to educate physicians and consumers about clinical features that make individual drugs more or less suitable—and more or less cost-effective—for specific patients. For example, the marketer of a branded, patented drug might provide published studies demonstrating that the drug is associated with a lower rate of side effects, complications, recurrences, or relapses than a generic drug (or a less expensive branded drug) in the same therapeutic class. Taking into account the cost of treating these undesirable outcomes, the total cost of treatment with the drug is actually less than the total cost of treatment with the generic—although more expensive on a unit price (or cost per course of therapy) basis; thus, the branded drug is more cost-effective than the generic. Increasingly, pharmaceutical firms are using promotional expenditures to demonstrate (and compete on the basis of) cost-effectiveness rather than unit drug price.

Regardless of how high promotional expenditures in the pharmaceutical industry are explained, one might expect new firms to be at a disadvantage with respect to more established firms if they must invest significantly in advertising to compete. The high promotional expenses required to compete add to the capital demands on new entrants. Despite the high cost of promotion, several economists in the late 1970s

determined empirically that industry promotional expenditures were positively related to market entry. Thus, new entrants use their promotional campaigns to achieve market entry. In a study of 17 therapeutic markets over the period 1969 to 1972, Tessler concluded that promotional expenditures actually facilitate entry because new products could not compete with existing products without being able to distinguish themselves through advertising.[45] Hornbrook found similar results and concluded that promotional expenditures serve more as a market penetration tool for new pharmaceutical manufacturers than as a barrier to entry.[46]

The three barriers to market entry discussed here—the high cost and substantial time involved in R&D, patent protection, and high promotional expenditures—clearly are not insurmountable, nor are they exclusively hindrances. Although it is extremely difficult to quantify the impact of such barriers on market competition, it is likely that established pharmaceutical companies have a degree of market power because of their established R&D operations and regulatory experience, patent protection, and reputations. Although the number of pharmaceutical establishments, particularly generics manufacturers, has grown over the past several decades, it is likely that competition in the industry would have been greater in the absence of the barriers to entry discussed above.

3.3.1.2 Concentration and Vertical Integration

The degree of concentration and vertical integration in a given industry is often used as an indicator of barriers to entry. Concentration is generally measured in terms of the percentage of value of shipments accounted for by a given number of firms in a particular industry. The U.S. Department of Commerce calculated 4-, 8-, 20-, and 50-firm concentration ratios for all 4-digit SIC industries through 1992 (see Table 3-15). The higher the concentration ratio in a given industry, the easier it is for manufacturers to set prices or to collude to set prices. Industrial economists have proposed that when the leading four firms control 40 percent or more of a given market, the market may be characterized by oligopolistic conditions that present significant barriers to entry.

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[45] As cited in Feldstein, Paul J., 1988. *Health Care Economics*. 3rd Edition. New York, NY: John Wiley & Sons.

[46] *Ibid*.

Table 3-15

4-, 8-, 20-, and 50-Firm Concentration Ratios:
SICs 2833, 2834, and 2836: 1954-1992

SIC Code	Year	Percent of Total Value of Shipments			
		4 Largest Companies	8 Largest Companies	20 Largest Companies	50 Largest Companies
2833 Medicinals and Botanicals	1992	76	84	91	97
	1987	72	80	89	95
	1982	62	75	85	94
	1977	65	78	89	96
	1972	59	75	90	98
	1970	64	74	NA	NA
	1967	74	81	91	98
	1966	70	81	NA	NA
	1963	68	79	91	99
	1958	64	77	89	98
	1954	72	84	93	NA
2834 Pharmaceutical Preparations	1992	26	42	72	90
	1987	22	36	65	88
	1982	26	42	69	90
	1977	24	43	73	91
	1972	26	44	75	91
	1970	26	43	NA	NA
	1967	24	40	73	90
	1966	24	41	NA	NA
	1963	22	38	72	89
	1958	27	45	73	87
	1954	25	44	68	NA
2836 Biological Products, Except Diagnostics	1992	53	71	86	96
	1987	45	65	80	93

NA = Not Available.
Source: U.S. Department of Commerce, 1995. *U.S. Census of Manufactures: 1992.* MC92-S-2. Washington, DC: U.S. Government Printing Office; U.S. Department of Commerce, 1991. *U.S. Census of Manufactures: 1987.* MC87-S-6 (CD-ROM). Washington, DC: U.S. Government Printing Office.

Table 3-15 lists the 4-, 8-, 20-, and 50-firm concentration ratios for SICs 2833, medicinal and botanicals; 2834, pharmaceutical preparations; and 2836, biological products, as reported by the U.S. Department of Commerce. As can be seen, the four leading firms in SIC 2833 controlled 76 percent of sales of SIC 2833 products in 1992. This situation contrasts to the four-firm concentration ratio of 26 percent in SIC 2834 and 53 percent in SIC 2836. There are almost three times as many companies in SIC 2834 as in SIC 2833. The relatively low four-firm concentration ratio of 26 percent in SIC 2834 and the relatively large number of companies suggests that barriers to entry in the pharmaceutical preparations sector of the industry are relatively insignificant compared with barriers to entry in the medicinals and botanicals sector. All of the concentration ratios increased between 1987 and 1992. These data suggest that the mergers, increased formation of megacompanies, strategic alliances/mergers with insurance companies, and selloffs of divisions of small- to medium-size companies in the late 1980s and early 1990s have increased vertical integration and concentration in the pharmaceutical industry.

Nevertheless, concentration ratios calculated for such large industry segments are of limited value. The overall drug market is fragmented into a number of separate, noncompeting therapeutic markets. Manufacturers of antibiotics, for example, do not compete with manufacturers of muscle relaxants. Thus, concentration ratios should be calculated and analyzed within the specific therapeutic markets in which manufacturers do compete. Only one study was identified in the economic literature of concentration ratios by therapeutic category. The study, conducted by Vernon, divided the prescription drug market into 19 therapeutic markets according to the degree of demand-side substitutability between different drugs (i.e., relatively close drug substitutes were placed in the same general therapeutic market).[47] The four-firm concentration ratios calculated by Vernon in the 19 therapeutic markets are presented in Table 3-16. As can be seen, all of the concentration ratios are quite high; the lowest ratio in a therapeutic market is 46 percent. Several concentration ratios are in the 90 percent range, and the unweighted average is 68 percent. Vernon's study suggests that a relatively small number of companies dominate sales in the individual therapeutic markets.

Even therapeutic market-specific concentration ratios might not present an accurate picture of competitive conditions in the pharmaceutical industry, however. According to Feldstein, concentration ratios

[47] Vernon, John M., 1971. Concentration, Promotion, and Market Share Stability in the Pharmaceutical Industry. *Journal of Industrial Economics* 19:246-266. July 1971.

Table 3-16

Concentration Ratios in the U.S. Prescription Drug Industry, By Therapeutic Market: 1968

Therapeutic Market	Four-Firm Concentration Ratio
Anesthetics	69
Antiarthritics	95
Antibiotics-penicillin	55
Antispasmodics	59
Ataractics	79
Bronchial dilators	61
Cardiovascular hypertensives	79
Coronary-peripheral vasodilators	70
Diabetic therapy	93
Diuretics	64
Enzymes-digestants	46
Hematinic preparations	52
Sex hormones	67
Corticoids	55
Muscle relaxants	59
Psychostimulants	78
Sulfonamides	79
Thyroid therapy	69
Unweighted average	68

Source: Vernon, John M., 1971. Concentration, Promotion, and Market Share Stability in the Pharmaceutical Industry. *Journal of Industrial Economics* 19:246-266. July, 1971.

are a static measure of market power.[48] Feldstein notes that although a particular therapeutic market can be characterized by high concentration at a given point in time, market shares in that therapeutic market can change radically over time. Instability in market shares over time indicates intense competition among firms through new product innovation. One study in the early 1970s noted that of the 20 industries investigated, only the petroleum industry possessed a higher degree of market instability than the pharmaceutical industry. Moreover, exit from and entry to the pharmaceutical industry seems to be quite high. In a study of 17 therapeutic markets between 1963 and 1972, 15 markets had five or more new entrants. Market exit occurred in 16 of the 17 markets.[49]

A high level of vertical integration might also indicate the presence of barriers to entry in a given industry. Vertical integration refers to the extent to which production inputs and services are produced and transferred within a given company, rather than procured from other companies. In the pharmaceutical industry, a vertically integrated firm might engage in R&D, several types of manufacturing (e.g., bulk drug manufacturing and finished product formulation), and marketing/ distribution. In the pharmaceutical industry, the two principal advantages of vertical integration are in ensuring confidentiality and achieving economies of scale.

Although production contracts with other companies contain confidentiality provisions, some firms choose vertical integration as a way of ensuring confidentiality, especially important when developing and launching new innovative drugs. Economies of scale occur when production inputs can be used to produce several different outputs. For example, cumulative drug R&D and promotional expenditures might be used jointly in the production of more than one drug product. Similarly, R&D studies, manufacturing processes, and regulatory experience established during the development and marketing of a branded drug might later be used to bring a generic equivalent to market very quickly and efficiently upon expiration of the branded drug's patent protection. Such economies of scale might serve as a barrier to entry in the pharmaceutical industry to the extent that the high costs associated with pharmaceutical R&D and promotion raise start-up

[48] Feldstein, 1988. *Op. cit.*

[49] *Ibid.*

costs and reduce the ability of new firms to raise sufficient capital to profitably enter the industry.[50]

Evidence from the Section 308 Survey provides some indication that pharmaceutical companies are vertically integrated. Of the 139 parent companies for which survey data are available, 129 have operations spanning all four of the industry's major production processes: fermentation (process A), biological and natural extraction (process B), chemical synthesis (process C), and formulation (process D). Three of the parent companies own facilities involved in processes A or C only, and 7 own facilities involved in processes B or D only. At the facility level, 150 of the 244 facilities surveyed engage in only one production process (101 of these firms engage only in formulation), 70 perform two production processes, 16 perform three production processes, and 8 engage in all four major production processes. Nearly 85 percent of the owner and parent companies reported R&D expenditures in the 3 years surveyed.

These data suggest that many pharmaceutical companies have chosen to integrate vertically, engaging in R&D, production of active ingredients, and formulation to take advantage of natural economies of scale that reduce the costs associated with developing and marketing new drugs. The surveyed pharmaceutical companies are not necessarily representative of the industry as a whole, however, because the survey focused on wastewater dischargers. As noted earlier, this group includes a greater proportion of large establishments—and probably a greater proportion of vertically integrated firms—than does the industry as a whole. Nevertheless, some degree of vertical integration clearly exists, and the survey data agree with observations that many major pharmaceutical companies are vertically integrated. As noted above, recent mergers of major pharmaceutical firms appear to have increased the size and degree of vertical integration of large firms, while recent sales of R&D or other divisions by smaller firms may have decreased the size and degree of vertical integration of those firms.

The effect of vertical integration on market structure and market performance cannot be quantified, but the data suggest that major pharmaceutical companies have a degree of market power. In fact, some analysts are predicting that one aspect of the trend toward greater vertical integration—the establishment of generic manufacturing divisions within major innovative pharmaceutical companies—may jeopardize the

[50] Vertical integration also can lead to economies of scale where the existence of fixed factors of production such as physical capital can cause unit costs to fall as output rises. It is generally assumed, however, that unit costs are constant across output levels in the pharmaceutical industry. Other advantages of vertical integration might include the ability to capture monopoly/monopsony inefficiency losses and engage in price discrimination (RTI, 1993. *Op. cit*.)

future of small independent generics firms, which might not be able to compete against large firms with much greater resources (see Section 3.3.3.1). If this trend continues as projected, the number of small generics firms might decline significantly.[51] A more recent report in the *Wall Street Journal* suggests that intense competition among the small independent firms and larger firms has, in fact, hurt some of the small firms; by contrast, the report indicates that small generics firms selling products with relatively little competition (including products in niche markets) are prospering.[52]

3.3.2 The Characteristics of Demand for Pharmaceuticals

Demand conditions for pharmaceutical manufacturers will help determine the impact of regulation-induced costs on market prices and outputs. This section examines various characteristics of demand, including the market demographics, the primary market outlets, and the effect of health insurance on the market.

Demand conditions vary significantly among specific drug markets. Differences in regulatory requirements and payment mechanisms are particularly important in determining demand. For example, in the prescription drug market (i.e., new drugs and generics), demand is complicated by the role of health care providers and the presence of health insurance. Unlike most consumer markets, consumers of prescription drugs are not directly involved in purchasing decisions; that is, they do not decide which drugs to take, for how long, and at what dosages. Health care providers act on the patient's behalf in deciding which medical treatment is most appropriate given the patient's health status, financial condition, and insurance coverage. These topics are discussed further below.

The demand for OTC (i.e., nonprescription) drugs, on the other hand, conforms more readily to standard models of consumer demand. OTC drugs are relatively easy to market, available without physician consent, and sold in a relatively competitive environment. Like the demand for other nondurables, the demand

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[51] Ukens, Carol, 1994. The Generic Industry '94: It's a Jungle Out There. *Drug Topics Supplement 1994*; Giltenan, Ed, 1994. The Copycat Shuffle. *Pharmaceuticals '94.* March 7.

[52] Eisinger, Jesse, 1996. Makers of Generic Drugs Are Expected to Post Mixed Results for First Quarter. *The Wall Street Journal.*

for OTC drugs is thought to be positively correlated with income and negatively correlated with price. Consumers identify a specific health need, such as relief from minor pain or cold symptoms, and then search for a product to satisfy that need. Because in most cases a variety of OTC products will meet a given need, demand is heavily influenced by advertising and price.

3.3.2.1 Market Demographics

Like the demand for health care generally, the demand for pharmaceuticals is derived from the demand for good health. A pharmaceutical is both a consumption commodity, since it makes the consumer feel better in the present, and an investment commodity, since it may extend the life of the consumer. Given this view of pharmaceutical demand, one would expect, all other things being equal, that the demand for pharmaceuticals will be dependent on factors such as the incidence of illness and sociodemographic factors like age, education, and income. Other factors, such as perceptions of the seriousness of medical conditions and belief in the efficacy of medical treatment, also influence pharmaceutical demand.

Among individuals, pharmaceutical demand is heavily concentrated in the segment of the population that includes people of age 65 and older. In fact, today between 30 and 40 percent of all pharmaceuticals are consumed by persons 65 years old and older.[53] This finding is not surprising given the strong correlation between age and health. As the U.S. population ages over the next several decades, the demand for pharmaceuticals will presumably rise. Since 1980, the number of people age 65 and older has increased at a rate more than twice that of the general population. By 1996, the U.S. Census Bureau predicts that 13 percent of the U.S. population will be over 65 years of age. The U.S. Department of Commerce cites the aging of the U.S. population (and the resulting growing market for chronic care medicines) as one of the main reasons it expects pharmaceutical sales to grow over the next few years.[54]

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[53] NatWest, 1992. *Op. cit.*

[54] U.S. Department of Commerce, 1993. *Op. cit.*; U.S. Department of Commerce, 1995. *Op. cit.*

3.3.2.2 Major Market Outlets

According to a 1991 study of the pharmaceutical market, retail and hospital pharmacies dispense over 84 percent of all pharmaceuticals sold in the United States (see Figure 3-9). Direct mail order establishments and HMOs, however, are capturing an increasing share of the market. Pharmaceutical purchases by hospitals have fallen by 6 percent since 1983. This drop is credited, in part, to changes in the Medicare system that have created incentives for hospitals to reduce inpatient services. Drugs once prescribed on an inpatient basis are now more likely to be prescribed on an outpatient basis and thus dispensed through retail pharmacies.[55]

3.3.2.3 The Role of Health Insurance and Health Care Providers

The demand for prescription drugs is influenced by the complex structure of health insurance and health care provision. It is generally believed that the presence of health insurance makes consumers relatively insensitive to the price of health care. Although not empirically measured, this relationship is expected to apply to the demand for pharmaceuticals as well. The full impact of health insurance on prescription demand is somewhat muted by deductibles and copayments; nonetheless, health insurance almost certainly makes consumers less sensitive to drug prices. As was noted many times during the recent health care reform debate, many privately insured Americans are protected from extraordinary medical costs and, thus, have little incentive to limit health care expenditures, including the use of prescription drugs. According to OTA, in 1987, 28 percent of all prescribed drug expenditures were paid for by private insurance, 10 percent by Medicaid, 6 percent by other insurers such as Medicare and Worker's Compensation, and 57 percent by individuals.[56]

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[55] OTA, 1993. *Op. cit.*

[56] Insurance coverage of pharmaceutical expenditures is less than that for health care generally. Approximately 75 percent of all health care expenditures are paid for by insurance; *ibid.*

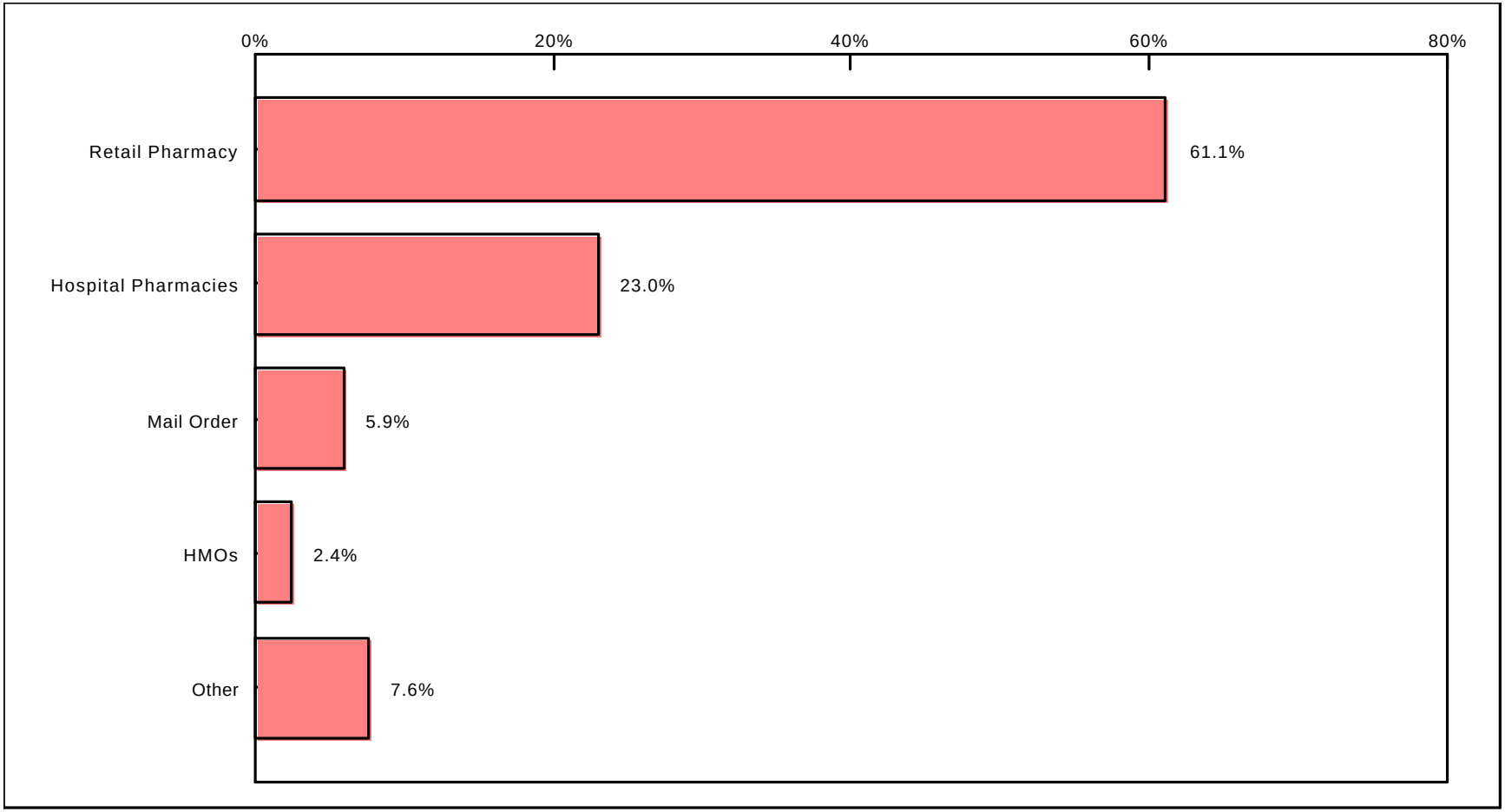

Figure 3-9. U.S. Pharmaceutical sales by retail component: 1991.

Source: U.S. Congress, Office of Technology Assesment, 1993. *Pharmaceutical R&D: Costs, Risks, and Rewards.* Washington, DC: U.S. Government Printing Office.

The percentage of Americans with public or private health insurance has risen steadily over the past decade to 86 percent today.[57] Virtually all health insurance plans cover hospital services, including prescription drugs administered at the hospital. As noted earlier, however, hospitals account for a declining share of total pharmaceutical sales in the United States, dropping from 29 percent in 1983 to 23 percent in 1991.[58] This drop can be attributed to a shift toward a greater reliance on outpatient services, which are often less expensive than hospital care.

Outpatient prescription drug insurance, although less common than inpatient coverage, covers an increasing proportion of Americans. The proportion of outpatient prescription drug purchases paid for by insurers increased from 27 to 43 percent between 1977 and 1987.[59] OTA estimates that in 1987, between 70 and 74 percent of the noninstitutionalized population had at least some outpatient prescription drug coverage. Very few health insurance plans cover 100 percent of prescription drug costs, however. Full coverage is most common in HMOs. Most health insurance plans rely on copayments to limit prescription drug use, although copayments are generally in the range of $5 or less.[60] Private insurers generally cover all drugs approved for market by FDA.[61]

The lack of price sensitivity among consumers is partly offset by increasing sensitivity among insurers. To control rising health care costs, many private and public insurers have moved to limit pharmaceutical expenditures. Many private insurers have created incentives for physicians and consumers to substitute generic drugs for branded drugs. OTA reports that in 1989, 14 percent of all employer-based health insurance plans offered lower copayments for generic drugs than for branded drugs. HMOs are particularly well suited to encourage generic drug utilization because they control physicians more directly than fee-for-service plans. Some HMOs require that their pharmacies automatically substitute generic drugs

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[57] OTA, 1993. *Op. cit.*

[58] *Ibid.*

[59] *Ibid.*

[60] *Ibid.*

[61] Insurance does not always cover uses of prescription drugs not explicitly approved by FDA. OTA reports that insurers are generally willing to reimburse for "off-label" uses that have been documented as effective in one of three major medical compendia or in multiple published studies. The so called off-label use of prescription drugs is common in many branches of medicine, especially in the treatment of cancer; *ibid.*

for branded drugs unless the physician explicitly instructs otherwise. HMOs and other insurers also try to reduce drug costs by negotiating with manufacturers for volume discounts and relying on direct mail-order pharmacies for drugs that patients need refilled on a regular basis. In fact, the U.S. Department of Commerce cites reports from economic research firms suggesting that the formation of large buying groups under managed care programs has served to moderate prescription drug prices; a more recent report from an industry analyst agrees with this finding.[62] Medicaid, the nation's major public health insurer, also creates incentives to keep drug costs low.

3.3.2.4 Substitutability Among Pharmaceuticals and With Other Medical Services

The availability of close substitutes plays an important role in determining competitive conditions in various drug markets. Generally, the greater the availability of close substitutes in a given market, the more difficult it is to raise prices without losing market share. Substitution occurs within specific drug markets or within the overall health care market (i.e., pharmaceuticals can substitute for other forms of health care), and both of these are discussed below.

Substitutability Among Pharmaceuticals

The degree of substitutability within or across specific drug markets varies considerably between the patented drug market, the generic drug market, and the OTC drug market.

Patented Drug Market. Patented drugs in the United States enjoy ostensible protection from bioequivalent drugs for a number of years. Effective patent life, however, reflects only the period of time in which a particular compound is formally protected from bioequivalent competitors. Manufacturers of patented drugs may enjoy market exclusivity for many years after patent expiration because of the time needed to approve generic competition, or because the particular market is too small to entice generic

[62] U.S. Department of Commerce, 1994. *Op. cit.*; Moore, 1996. *Op. cit.*

competitors.[63] In addition, manufacturers of patented drugs may be able to extend their monopoly power after patent expiration by developing new dosage forms for the same drug. The 1984 Price Act automatically grants a 3-year period of market exclusivity, regardless of patent status, to any drug for which an additional full NDA or NDA supplement has been submitted. With a new dosage form that makes a drug easier to administer or causes fewer side effects, the "pioneer" manufacturer can retain effective monopoly power because its competitors can only market the earlier, and presumably inferior, generation of the product.

The availability of close substitutes for many patented drugs, however, significantly erodes the monopoly power enjoyed by these manufacturers. Drugs of different molecular structure often can compete in the same therapeutic market. For example, four classes of drugs (calcium channel blockers, angiotensin-converting enzyme inhibitors, beta-blockers, and diuretics, each of which contains several branded drugs) all compete in the mild-to-moderate antihypertension drug market; additional classes of drugs compete in the moderate-to-severe antihypertension drug market. Between 1987 and 1992, 78 percent of the new drugs approved by FDA were deemed substantially equivalent to already marketed drugs in terms of medical importance and therapeutic usage.[64] Thus, it would seem that although patents certainly reduce the availability of identical substitutes during the life of the patent, physicians in many cases can choose from more than one drug therapy to treat a given ailment.

Generic Drug Market. The ascendancy of generic competitors in the prescription drug market has greatly increased the availability of substitutes in the nonpatent drug market. Prior to the 1984 Price Act, generics accounted for a low percentage of total prescriptions given their relatively low price and FDA-guaranteed bioequivalence. Brand loyalty, strict FDA regulation, and state antisubstitution laws that prevented pharmacies from making generic substitutions not specifically requested by a physician all acted to reduce the ability of generics to compete with branded prescriptions. Over the past decade, however, generic competition has increased dramatically, and today generics account for 34 percent or more of all prescriptions written.

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[63] U.S. patent law prohibits companies from conducting commercially valuable research using patented products.

[64] FDA, 1992. *Op. cit.*

The rise in generic competition is the result of several factors. Perhaps most importantly, both private and public insurers (i.e., Medicaid/Medicare) encourage, if not require, physicians to prescribe generic drugs when available (virtually all states have repealed their antisubstitution laws). Many HMO pharmacies now automatically prescribe generic drugs unless the physician makes a handwritten request for a branded drug. As mentioned earlier, the 1984 Price Act made it easier for generics to obtain FDA approval as well. In a recent study of 18 drugs whose patents expired in 1983, Grabowski found that nearly all of the manufacturers lost about half of their market share to generic competition within 2 years after initial entry of generic competitors.[65]

OTC Market. As discussed earlier, the OTC market is much like other competitive commodity markets where there is a high degree of substitutability and demand is relatively sensitive to changes in price. OTC drugs do not face the same regulatory hurdles as prescription drugs and generally do not require such large R&D expenditures. Unlike many prescription drug markets, most OTC drug markets are quite large and thus capable of sustaining many manufacturers of the same product.

Substitutability With Other Medical Services

Physicians typically can serve the patient in the hospital setting or they can provide ambulatory (i.e., outpatient) services, such as prescription medicines. For certain conditions, pharmaceuticals might be a very close substitute for inpatient services (e.g., hospitalization, surgery). For example, instead of performing surgery, a doctor might prescribe antibiotics to treat infected tonsils or antibiotics plus renally acting drugs to treat a benign enlargement of the prostate gland. Alternatively, a doctor might prescribe medications as a means of reducing hospital stays for surgery; for example, use of antibiotics to prevent infection can reduce the length of stay required for many types of surgery, while use of blood cell growth factors can reduce the length of stay required for bone marrow transplants (which are among the most expensive procedures performed in hospitals today). In addition, the use of medicines reduces the prevalence of some medical conditions that might otherwise require expensive hospital treatment; for example, the use of vaccines

[65] Grabowski, Henry G., and John M. Vernon, 1992. Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act. *Journal of Law and Economics* 35(2):331-350. October 1992.

reduces the prevalence of infectious diseases such as polio, diphtheria, and hepatitis, while the use of antihypertensive medications reduces the prevalence of heart attack, congestive heart failure, and stroke.

Some argue that pharmaceuticals can provide a relatively low-cost alternative to other available medical treatments. In 1989, PhRMA, then called the Pharmaceutical Manufacturers Association (PMA), estimated that between 1976 and 1985 a new drug therapy for ulcers reduced the cost of treating ulcers by $5.8 billion.[66] More often, though, pharmaceuticals complement rather than replace other forms of health care. Many surgical procedures are accompanied by pharmaceutical use both during and after surgery, and pharmaceuticals are often used to diagnose diseases that are then treated with surgery and/or medicine. In general, therefore, pharmaceuticals are not a very close substitute for most forms of medical treatments.

Overall, the extent of substitutability is fairly low. Few pharmaceuticals can be replaced by nonpharmaceutical products and services, although more than one pharmaceutical product is often available to treat a given ailment. The degree of substitution in the prescription drug market increases over time as patents expire and generic equivalents enter the market. Substitution is highest in the OTC market where market entry is relatively easy.

3.3.2.5 Price Elasticity of Demand

Few econometric studies have attempted to measure empirically the effect of price on the demand for pharmaceuticals (i.e., the price elasticity of demand). Four such studies have been published,[67] although only one was conducted in the United States. Their elasticity estimates are presented in Table 3-17, and the results are discussed below.

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[66] Pharmaceutical Manufacturers Association (PMA), 1989. *Pharmaceutical Manufacturers Association Annual Report.*

[67] Reekie, Duncan W., 1978. Price and Quality Competition in the United States Drug Industry. *The Journal of Industrial Economics* 26(3):223-237; Lavers, R.J., 1989. Prescription Charges, the Demand for Prescriptions and Morbidity. *Applied Economics* 21:1043-1052; O'Brien, Bernie, 1989. The Effect of Patient Charges on the Utilization of Prescription Medicines. *Journal of Health Economics* 8:109-132; Johnston, 1991. As cited in RTI, 1993. *Op cit.*

Table 3-17

Estimates of the Price Elasticity of Demand for Prescription Drugs

Study Author	Elasticity Estimates	Study Time Frame	Comments
Reekie, 1978. *Op. cit.*	-1.03 to -2.83	1958-1975	Study of individual pharmaceutical products within 25 therapeutically competitive markets. Price of close substitutes included in regression estimate. Calculated separate estimates for therapeutically significant and insignificant drugs.
Lavers, 1989. *Op. cit.*	-0.15 to -0.20	1971-1982	Study of increases in prescription charges for a wide range of pharmaceuticals in the U.K.
O'Brien, 1989. *Op. cit.*	-0.23 -0.64	1969-1977 1978-1986	Study of increases in prescription charges for a wide of range of pharmaceuticals in the U.K.
Johnston, 1991. *Op. cit.*	-0.5	NA	Study of increases in prescription charges for a wide range of pharmaceuticals in Australia.

NA = Not Available.

In separate studies, O'Brien and Lavers estimated the effect on demand for a wide range of prescription drugs given an increase in the copayment demanded by Great Britain's National Health Service (NHS).[68] Between 1969 and 1986 the charge for prescription drugs increased substantially in Great Britain from 0.125£ per prescription in 1969 to 2.20£ in 1986 (£1986), an increase in real terms by a factor of 17.6. The ratio of patient charges to actual drug cost also more than doubled over that same time period from 0.21 in 1969 to 0.43 in 1986. The patient charge was a fixed rate and did not vary by prescription type. Men over the age of 65, women over the age of 60, children under 16, and low income groups were exempt from the prescription charges. Approximately 24 percent of the 323 million prescription items dispensed in 1986 included an associated charge.

Both O'Brien and Lavers found a negative relationship between prescription charges and the volume of nonexempt prescription items dispensed. O'Brien's study estimated a price elasticity of demand over the entire period of -0.33, indicating that a 1 percent increase in patient charges leads to a 0.33 percent decrease in prescription drug use. O'Brien also discovered that there has been a gradual change over time in the elasticity. For the period 1969 to 1977, O'Brien calculated a price elasticity of -0.23. Elasticity increased in his study, however, to -0.64 between 1978 and 1986. This finding suggests that prescription drug use became more responsive to price between the study periods. Using similar data, Lavers found an elasticity of demand between -0.15 and -0.20 for the period 1971 to 1982, remarkably close to O'Brien's 1969-1978 estimate.

Johnston studied a similar situation in Australia where federal policies led to a doubling of prescription charges for a large group of pharmaceuticals in the 1970s.[69] Johnston's estimate of -0.5 indicates slightly more elastic demand than indicated by studies by O'Brien and Lavers.

The studies conducted by O'Brien, Lavers, and Johnston do not consider the possibility of substitution among drug products within specific therapeutic markets, and thus do not provide a complete measure of demand elasticity for individual drug products. Reekie accounts for product substitution by including the price of therapeutically competing drugs in the estimating equations for individual prescription

[68] O'Brien, 1989. *Op. cit*.; Lavers, 1989, *Op. cit.*

[69] Johnston, 1991. *Op. cit*.

drugs within therapeutic categories.[70] Using this method, Reekie found more elastic demand than either O'Brien, Lavers, or Johnston. Reekie's estimates ranged from -1.03 to -2.83, depending on the therapeutic significance of the drug and how many years the drug had been on the market. Predictably, Reekie's estimates were most elastic for drugs that had been on the market for a number of years and offered only modest therapeutic gains, and most inelastic for recently introduced drugs that provided important therapeutic gains.

Although these empirical studies are hardly conclusive regarding price elasticity, they do indicate that the demand for pharmaceuticals as a group may be quite inelastic (i.e., between 0 and -1.0), whereas the demand for a specific drug product may be relatively elastic (i.e., less than -1.0). The absence of close substitutes for drug therapies in general and the presence of health insurance leads one to expect that the overall demand for pharmaceuticals would be inelastic. Conversely, given the existence of close substitutes for individual drugs (e.g., generics and other therapeutically similar drugs) and the pressure to control health care costs, the demand for specific drugs may be relatively price elastic.

3.3.3 Market Conduct and Performance

To predict regulatory impacts, it is necessary to examine not only how the pharmaceutical industry is structured, but how it behaves. The pharmaceutical industry has been under attack for its seemingly uncompetitive pricing tactics, for having excessive market power related to patent protection advantages, and for other potential barriers to entry discussed above. This section explores the numerous factors pharmaceutical manufacturers consider when setting drug prices, examines the evidence on drug price inflation, and discusses some of the recent actions taken by both industry and government to control drug prices.

A basic element of market performance is the rate of price inflation. The price of drugs has outpaced the rate of general inflation over the last several decades. Table 3-18 presents producer price indices (PPI) for selected drug categories including all drugs, single-source drugs, and multiple-source drugs for selected years between 1981 and 1988. As can be seen in the table, the rate of increase in the PPI for almost all drug types outpaced inflation (i.e., the change in PPI for all commodities) in the 7 years studied.

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[70] Reekie, 1978. *Op. cit*.

Table 3-18

Change in Producer Price Index for Pharmaceuticals: 1981-1988

Commodity	Percent Change in PPI 1981-1988	Average Annual Percent Change in PPI	Annual Percent Change in PPI						
			1982	1983	1984	1985	1986	1987	1988
All commodities	9.1	1.3	2.0	1.3	2.4	-0.5	-2.9	2.6	4.0
All drugs	83.5	9.1	7.3	9.5	9.6	9.6	8.7	8.7	10.1
Single-source drugs	78.1	8.6	7.6	7.3	9.8	10.2	8.1	7.3	9.9
Multiple-source drugs	85.8	9.3	7.2	10.4	9.5	9.3	9	9.4	10.1
Originator	105	10.8	8.9	12.9	11.5	10.5	10.4	10	10.9
Non-originator	20	2.7	2.1	0.7	-0.5	3.3	2.1	4.7	6.3

Source: HCFA, 1992. Health Care Financing Administration. Pharmaceutical Price Changes: 1981-1988. *Health Care Financing Review* 14(1): 90-105. Fall 1992.

A General Accounting Office report, however, indicates that the government's index overstated drug inflation between 1984 and 1991 by 23 to 36 percent due to a failure to take into account the impact of new, recently introduced medicines.[71] Recent PPI data from the Bureau of Labor Statistics seems to support this idea. According to the Bureau of Labor Statistics, the PPI for pharmaceuticals has been under 10 percent since 1989 and has steadily declined–so much so that the PPI for pharmaceuticals approached the general rate of inflation in 1994 (see Table 3-19). Some have viewed these statistics as indicating that market pressures are working to moderate drug prices. Indeed, the U.S. Department of Commerce has noted that market pressures have led 10 of the leading pharmaceutical firms to promise to increase their average prices at a rate no greater than the general inflation rate.[72]

Even the higher levels of drug price inflation in previous decades have not matched the inflation rate for medical care generally. Table 3-20 lists consumer price indices (CPI) for medical care generally, prescription drugs, hospital rooms, and physician services between 1950 and 1985. According to these data, the CPI for drugs rose 187 percent between 1950 and 1985, in contrast to the much larger CPI increases in medical care (651 percent between 1950 and 1985) and hospital rooms (2,245 percent between 1950 and 1985) over the same time period. Interestingly, between 1950 and 1985, the CPI for drugs rose less than the rate of inflation (i.e., the change in CPI for all goods and services). In 1986 through 1992, however, the CPI for drugs increased approximately twice as much as the general rate of inflation in most years (see Table 3-21). More recently, the CPI for prescription drugs has increased more closely to the rate of inflation. Over the years 1986 through 1997, CPI for drugs increased by 91 percent compared to 46 percent associated with CPI for all items, or roughly double the rate of inflation..

3.3.3.1 Patterns of Price Competition

Manufacturers have considerable latitude to set prices according to factors other than marginal cost, such as reputation, demand conditions in different markets (e.g., hospital v. retail), and the company's long-

[71] U.S. General Accounting Office (GAO), 1995. *Prescription Drug Prices*: *Official Index Overstates Producer Price Inflation*. Washington, DC: U.S. GAO.

[72] U.S. Department of Commerce, 1994. *Op. cit.*

Table 3-19

Change in Producer Price Index for Pharmaceuticals: 1988-1997

Commodity	Percent Change in PPI 1988-1997	Average Annual Percent Change in PPI	Annual Percent Change in PPI								
			1989	1990	1991	1992	1993	1994	1995	1996	1997
All commodities	19.4	2.0	5.0	3.7	0.2	0.6	1.5	1.3	3.5	2.4	-0.1
All drugs (SIC 283)	47.6	4.3	7.7	6.4	6.5	6.1	4.0	1.4	2.4	1.8	2.0

Source: http://146.142.4.24/cgi-bin/surveymost

Table 3-20

Change in Consumer Price Index for Pharmaceuticals and Selected Health Care Services: 1950-1985

Year	Percent Change from Previous Year				
	All Goods and Services (%)	**Prescription Drugs (%)**	**Medical Care (%)**	**Hospital (Semiprivate Room) (%)**	**Physician Services (%)**
1950	NA	NA	NA	NA	NA
1955	9.4	9.7	20.7	39.6	18.5
1960	10.4	13.5	22.1	35.5	17.7
1965	6.4	-11.5	13.1	32.5	14.7
1970	23.2	-0.8	34.7	91.6	37.5
1975	38.7	8.0	39.8	62.4	39.5
1980	53.2	41.6	57.7	77.4	59.0
1985	30.6	71.5	51.6	69.6	48.1
1950-1985	**339.2**	**186.7**	**650.7**	**2,244.9**	**622.5**

NA = Not Available

Source: Feldstein, Paul J., 1988. *Health Care Economics*. 3rd Edition. New York, NY: John Wiley & Sons.

Table 3-21

Pharmaceutical and General Inflation Indicators: 1986-1997

Year	CPI for All Items (%)	CPI for Prescription Drugs (%)	CPI for Medical Care (%)
1986	1.1	9.0	7.7
1987	4.4	8.0	5.8
1988	4.4	7.8	6.9
1989	4.6	9.5	8.5
1990	6.1	9.9	9.6
1991	3.1	9.4	7.9
1992	2.9	5.7	6.6
1993	2.7	3.3	5.4
1994	2.7	3.3	4.9
1995	2.5	2.0	3.9
1996	3.3	3.4	3.0
1997	1.7	2.6	2.8
% change from 1986 to 1997	**46%**	**91%**	**92%**

Source: Council of Economic Advisors, 1998. *Economic Report of the President: 1998.* Washington, DC: U.S. Government Printing Office; U.S. Bureau of the Census, 1997. *Statistical Abstract of the United States, 1997.* Washington, DC; U.S. Government Printing Office.

run financial goals.[73] Ultimately, the prescription drug manufacturer must establish a price that can recover the long-run costs associated with pharmaceutical R&D. Typically, manufacturers of patented drugs will set initial price well above marginal cost with the understanding that demand for the product will most likely be fairly inelastic at least until the patent expires and close substitutes become available. The manufacturer uses the time between market launch and patent expiration to recoup R&D costs and generate sufficient profits to finance new product development. The prescription drug manufacturer will devote considerable resources to promoting its product during this period, convincing physicians and patients of the drug's therapeutic benefits and establishing itself as the supplier of the drug in anticipation of generic competition.

Once the patent expires for a given prescription drug, price competition becomes a greater consideration. Because patented drugs will have garnered a certain level of brand loyalty from physicians, generic drug manufacturers must enter the market with a relatively low price to establish market share. According to NatWest Investment Banking Group, which monitors the generic industry, the first generic manufacturer to enter a given market generally prices its drug around 30 percent below the brand-name drug and realizes a gross margin of about 55 percent. The second generic manufacturer to enter a market usually prices its product at about a 40 percent discount, and the third entrant at about a 50 percent discount. NatWest estimates that by the time the fourth generic manufacturer enters a market, generics prices are half of brand-name prices and gross margins will have fallen to 30 percent or less.[74] The advantage of being the first generic entrant in a given market is clear.

Contrary to expectations, manufacturers of branded drugs do not attempt to deter entry into their markets by competing with generics on the basis of price. Rather, studies show that in most cases pioneer firms continue to increase prices following entry at the same rates as before patent expiration. Some industry experts believe that brand-name drug manufacturers do not have the same force or breadth of product line to compete with the major generic manufacturers on the basis of price.[75] Branded manufacturers trust that despite the relatively high price of their drug, physicians will continue to prescribe their drug over generic

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[73] Evidence suggests that because of the wide availability of close substitutes in the OTC drug market, OTC drug manufacturers generally act as price takers. It is assumed, therefore, that OTC prices approximate marginal cost.

[74] NatWest, 1992. *Op. cit.*

[75] *Ibid.*

drugs because they are familiar with it and because many question the quality of generic drugs even though they have been deemed bioequivalent by FDA. Nonetheless, studies show that branded drugs lose market share rapidly following patent expiration. According to one study, brand-name drug market shares decline to only 40 percent within 5 years following patent expiration.[76] Within 6 years, brand-name drugs command only 20 percent of the market. In its study of the industry, OTA made various market analyses using an assumption that within 10 years brand-name drugs will have left the market altogether.[77]

Because branded drugs lose market share so rapidly after patent expiration, and because cost pressures are encouraging even heavier reliance on generics once they become available, many major pharmaceutical firms that previously specialized in new drug development and marketing are now establishing divisions or subsidiaries that manufacture and market generic versions of their own branded products—or they are purchasing or affiliating with previously independent generics firms.[78] In this way, these companies are keeping in house product sales (albeit at a lower margin than branded product sales) that otherwise would go to outside generics manufacturers. Moreover, major innovative firms selling generic versions of their own branded products may have a competitive advantage over small independent generics firms because:

- Pharmacists may be more likely to buy generic formulations from brand-name manufacturers because they know the generics will be exactly the same as the brand-name products (rather than equivalents that other firms have developed).

- Innovative firms already have study data, bulk chemical sources, and manufacturing processes in place, so they may be able to submit ANDAs and bring generics to market more quickly and less expensively than can small independent firms.

- Innovative firms have more money than small independent firms to spend on developing and producing generics.[79]

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[76] Grabowski, 1992. *Op. cit.*

[77] OTA, 1993. *Op. cit.*

[78] Ukens, 1994. *Op. cit.;* Giltenan, 1994. *Op. cit.*

[79] Ukens, 1994. *Op. cit.*

For these reasons, the trend toward generics manufacturing by major pharmaceutical firms may threaten the survival of some generics firms, especially the smaller ones. In addition, increasing domination by major pharmaceutical manufacturers could increase their market power, permitting them to set higher prices for their generics—at 20 percent below the price of the branded product, for example, rather than the more usual 30 percent discount for a first generic entrant. Given the pressure to keep prices down, however, major pharmaceutical firms are not expected to increase the price of generics very substantially.[80] A more recent report in the Wall Street Journal seems to substantiate this prediction, noting that intense competition among generics firms (as well as between generics firms and large pharmaceutical firms) appears to be keeping drug prices in check, in one case driving down a product price by 90 percent.[81] This report noted that this level of competition is hurting some generics firms, although those in niche markets or with other products having little competition are faring quite well.

3.3.3.2 Government Actions to Limit Pharmaceutical Price Increases

In the last several years, industry as well as state and federal governments have taken measures to control drug price inflation. As noted above, for example, 10 companies with over 40 percent of the U.S. pharmaceutical market share agreed in 1990 to keep drug prices in line with inflation.[82] PhRMA, which has spearheaded the effort, continues to enlist new companies in the price control program. Today, 16 pharmaceutical companies in all have agreed to keep increases in the price of their products at or below the rate of inflation.

Federal and state governments have recently taken steps to control drug prices through the Medicaid system. Medicaid provides health insurance for U.S. citizens of limited financial means and is funded jointly by states and the federal government. Medicaid currently covers outpatient prescriptions in 49 states and the District of Columbia, and accounts for nearly 15 percent of all outpatient prescription drug expenditures in

[80] Ukens, 1994. *Op. cit.*

[81] Eisinger, 1996. *Op. cit.*

[82] Solomon, Jolie, 1993. Drugs: Is the Price Right? *Newsweek*. March 8, 1993. pp. 38

the U.S. today.[83] Retail pharmacies dispense prescriptions at little or no cost to Medicaid recipients. State Medicaid agencies then reimburse pharmacies according to specified price tables. Some 22 states require copayments ranging between $0.50 and $3.00 per prescription.[84] States must cover all drugs approved by the FDA.

The 1990 Omnibus Budget Reconciliation Act (PL 10 1-508) altered state Medicaid reimbursement policies. Prior to 1990, state Medicaid agencies reimbursed pharmacies according to the pharmacy's acquisition cost plus a reasonable markup for single-source drugs, at no more than 150 percent of the lowest published price for multiple-source drugs.[85] In 1990, however, Medicaid instituted a new reimbursement scheme whereby pharmaceutical manufacturers must give state Medicaid agencies a rebate on their drug purchases. The rebate is designed to keep the cost of Medicaid drugs at or below the rate of inflation. Beginning in 1994, Medicaid instituted more stringent reimbursement policies that created strong disincentives for manufacturers to introduce drugs at above-average prices. The law can reduce revenues for manufacturers in the Medicaid segment of the pharmaceutical market. Any health care reform or changes made as part of federal budget debates could significantly alter federal or state administration of Medicaid and might include new incentives for controlling health care costs generally and drug costs in particular.

The general trend toward cost-containment in the health care field appears to have increased—and is likely to continue to increase the level of price competition in the prescription drug market. Thus, administrative actions as well as consumer and market behavior combine to determine pricing patterns in the industry.

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[83] OTA, 1993. *Op. cit.*

[84] *Ibid.*

[85] Single-source drugs are those available from only one manufacturer (i.e., a patented name-brand drug). Multiple-source drugs are available from several manufacturers (i.e., generics).

3.3.4 Conclusions About EA Assumptions on Cost Passthrough Potential

Because regulatory costs associated with the Final Pharmaceutical Industry Effluent Guidelines can affect a large portion of the industry, the industry as a whole might be able to pass through regulatory costs to the consumer in the form of higher drug prices. Individual companies (especially those marketing generic and OTC drugs), however, will have less latitude to raise prices to the extent that their competitors do not face the same regulatory costs. Nevertheless, many companies appear to have sufficient market power to pass through regulatory costs.

The price elasticity data also suggests that at least some of the regulatory costs can be passed on to consumers. The price elasticity studies indicate that demand is highly inelastic in the case of patented drugs with no substitutes (in the range of -0.2 to -0.4), mildly inelastic for generic drugs (-0.6 to -0.8), and elastic for OTC drugs (less than -1.0). Thus, if the EA distinguished among these three market segments, regulation-induced price increases in each component of the industry could be examined. Product-specific cost and price data were, however, not available from the Section 308 Pharmaceutical Survey, thus the EA can examine impacts only on the drug market as a whole.

Despite the evidence relating to market power and price elasticities, the EA primarily will use the conservative assumption that manufacturers cannot pass through compliance costs except when impacts on consumers are investigated. In this latter case a 100 percent cost passthrough assumption is used. The assumption of no cost passthrough maximizes the estimated regulatory impacts on manufacturers, whereas an assumption of 100 percent cost passthrough maximizes the estimated regulatory impacts on consumers.

SECTION FOUR

ECONOMIC IMPACT ANALYSIS METHODOLOGY OVERVIEW AND COMPLIANCE COST ANALYSIS

This section covers several components necessary for identifying and characterizing the potential impacts of regulatory compliance costs of the Final Pharmaceutical Industry Effluent Guidelines at the facility and owner-company levels and other potential secondary impacts. Section 4.1 provides an overview of the methodology used in analyzing the economic impact of the regulatory compliance costs. Section 4.2 discusses the cost annualization model, which is the fundamental component of this methodology. Section 4.3 summarizes the results calculated using this model (i.e., the total annualized cost of compliance for the pharmaceutical industry as a whole for each of the regulatory options considered), and Section 4.4 presents the total costs of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

4.1 METHODOLOGY OVERVIEW

Together, the regulatory analyses presented in this EA offer a comprehensive assessment of economic impacts at all relevant levels of activity. Figure 4-1 shows how the three principal models used in the EA (the cost annualization model, the facility closure model, and the owner company model) relate to one another, the inputs required for these models, and the outputs they generate. At the heart of the EA is the cost annualization model, which uses facility-specific cost data and other inputs (from EPA's Development Document) to determine the annualized capital and operating and maintenance (O&M) costs of improved wastewater treatment. Annualized cost data feed into the facility analysis, which models the economic impacts of regulatory costs on pharmaceutical facilities, irrespective of ownership. The firm-level analysis examines the possible effects of increased regulatory costs on companies that own multiple affected pharmaceutical establishments and also gauges the ability of all firms to raise the capital necessary to purchase and install pollution control equipment. Firms might be able to cover the costs of pollution control, but be too weak financially to attract the capital to make the purchase. The EA then explores impacts on employment and other measures of community welfare. Additional analyses examine whether increased compliance costs will affect domestic or international markets, inflation, new sources, or small businesses.

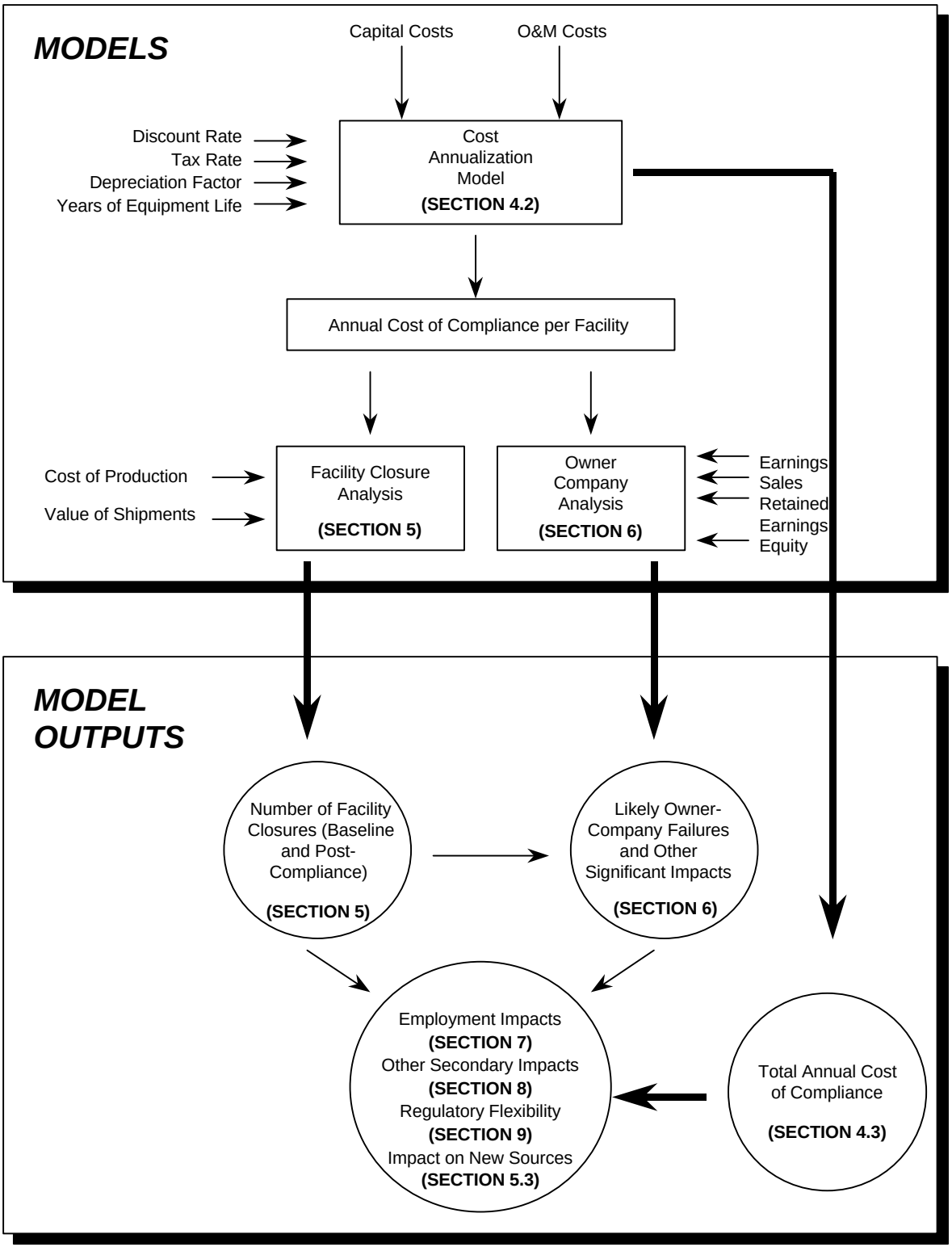

Figure 4-1. Interrelationship of EA methodology components.

4.2 COST ANNUALIZATION MODEL

4.2.1 Purpose of Cost Annualization

The cost annualization model estimates each facility's annual compliance cost on the basis of the costs required to purchase and operate new pollution control equipment for each Final Pharmaceutical Industry Effluent Guidelines option (or MACT standards cost). Cost annualization calculations consider the changes in annual cash outflow for each facility due to pollution control expenditures, once the tax effects of these expenditures (e.g., depreciation tax shields) are taken into account. Pollution control expenditures can be divided between two components: the initial capital investment to purchase and install the equipment and the annual cost of operating and maintaining such equipment (O&M costs). Capital costs are a one-time expense incurred only with the acquisition of the equipment, while O&M costs are incurred every year of the equipment's operation. The engineering cost model used to estimate facility compliance costs defines both capital and O&M costs.[1]

To determine the economic feasibility of upgrading a facility, the costs of compliance must be compared to each facility's precompliance cash flow.[2] Pollution control costs cannot be directly compared to first-year facility cash flow, however; the capital costs must be annualized, reflecting the fact that capital equipment costs are incurred only once and can be financed (i.e., spread out over the equipment's lifetime).

In the model, EPA calculates total annualized costs by allocating the capital investment over the lifetime of the equipment, using a cost-of-capital factor to address the costs associated with raising or borrowing money for this investment, and adding in annual O&M costs. The resulting annualized cost

[1] Cost data are from EPA's Development Document.

[2] As will be discussed in Section Five, EPA did not have data to develop facilities' precompliance cash flow. EPA used a proxy for cash flow that is likely to be a conservatively low estimate of actual cash flow. See Section Five for more information.

represents the average annual payment a given company will need to make to upgrade its facility.[3] EPA investigates in the firm-level analysis whether a firm can raise the capital to make the investment.

4.2.2 Inputs, Assumptions, and Model Outputs

4.2.2.1 Regulatory Options

The EA discusses a more limited set of options than is set forth in the Development Document. The options that are not discussed in the EA are primarily the no-action options (implicit in the baseline analyses discussed in Sections Five and Six), and a number of options that were rejected for reasons other than economic achievability. Discussions of why these options were rejected appear in the Development Document. Additionally, Best Conventional Control Technology (BCT) is not discussed here. The BCT cost test (the economic measure this regulation must meet) is undertaken in the Development Document.

The options that remain for discussion in the EA include:

- Best Practicable Control Technology (BPT), which is currently in place, but EPA is revising;
- Best Available Control Technology Economically Achievable (BAT), which has been developed assuming a revised BPT standard is in place;
- New Source Performance Standards, which are identical to the BAT options;
- Pretreatment Standards for Existing Sources (PSES);
- Pretreatment Standards for New Sources (PSNS), which include the same option as PSES.

[3] The annualized cost is analogous to a mortgage payment, which spreads the one-time investment in a home into a series of continual monthly payments. An annualized cost approach also more closely reflects how companies report expenditures on pollution control equipment. This equipment must be capitalized, not expensed according to IRS requirements: The equipment can be depreciated, but the total cost of the equipment cannot be subtracted from income in the first year (Commerce Clearinghouse, Inc., 1995. *U.S. Master Tax Guide*, 1995; and Research Institute of America, Inc., 1995. *The Complete Internal Revenue Code* [Section 169]. New York, NY: Research Institute of America, Inc., January).

See Table 4-1 for a description of these options, an option name that corresponds with the option name used in the Development Document, and a shortened name that will be used in the EA.

EPA's selected options are as follows:

- A/C Directs: BPT-A/C and BAT-A/C; NSPS-A/C for new sources
- B/D Directs: BPT-B/D and the no-action BAT alternative (not shown in Table 4-1). NSPS no-action alternative (not shown in Table 4-1) for new sources
- A/C Indirects: PSES-A/C; PSNS-A/C for new sources
- B/D Indirects: PSES-B/D; PSNS-B/D for new sources.

Note that the selected NSPS and PSNS options are identical to those selected for existing sources.

4.2.2.2 The Cost Annualization Model Parameters

Table 4-2 presents the cost annualization model using assumed data for illustrative purposes. The inputs and assumptions for the analysis are listed above the spreadsheet. The first input is the *facility code* for the facility analyzed. The second and third lines are the *facility type* (e.g., A/C) and discharge type (e.g., direct). The third line presents the regulatory *option* or alternative for which the annualized costs are calculated.[4] The fourth and fifth lines are the option's *capital* and *O&M* costs (from EPA's Development Document). For comparison purposes, costs are provided in terms of 1990 dollars.

The *life of the asset* is determined according to the Internal Revenue Code's classes of depreciable property. Fifteen-year property is assumed to have a class life of 20 to 25 years—a typical life span for the equipment considered in the costing analysis. According to the U.S. Master Tax Guide, 15-year property includes such assets as municipal wastewater treatment plants.[5] Thus, for the purposes of calculating depreciation, most components of the capital cost for a pollution control option would be considered 15-year property.

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[4] The terms "option" and "alternative" are used interchangeably in this section.

[5] Commerce Clearinghouse, Inc., 1995. *U.S. Master Tax Guide*. p. 322.

Table 4-1

Summary of Regulatory Options Considered In Economic Analysis[a]

Regulation	Short Option Description for EA Only	Option	Type of Treatment
BPT	BPT-A/C	Revise COD and modify cyanide	Advanced biological treatment
	BPT-B/D	Revise COD and withdraw cyanide	Advanced biological treatment
BAT	BAT-A/C	Add organics, ammonia, and COD and modify cyanide	Advanced biological treatment with nitrification
	BAT-B/D	Add COD and withdraw cyanide	Advanced biological treatment
NSPS	NSPS-A/C	Promulgated level of BPT/BAT control	Advanced biological treatment with nitrification
	NSPS-B/D	Promulgated level of BPT/BAT control	Advanced biological treatment
PSES	PSES-A/C	Add organics, ammonia,and modify cyanide	In-plant steam stripping for organic compounds and ammonia
	PSES-B/D	Add organics and withdraw cyanide	In-plant steam stripping for organic compounds
PSNS	PSNS-A/C	Add organics, ammonia, and modify cyanide	In-plant steam stripping for organic compounds and ammonia
	PSNS-B/D	Add organics and withdraw cyanide	In-plant steam stripping for organic compounds

[a] Many other options were considered and rejected for reasons other than economic achievability. See EPA's Development Document. Also, no-action options are included for all regulations. BCT is not analyzed in the EA. See the Development Document.

Source: U.S. EPA, 1998. *Technical Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*.

Table 4-2

Sample Spreadsheet for Annualizing Costs

Inputs

Facility Code:	30387
Facility Type:	A/C
Discharge Type:	Direct
Option:	BAT
Initial Capital Cost ($) (Line A):	$614,487
Annual Operation & Maintenance Cost ($) (Line B):	$58,710
Life of Asset (yrs.)	15
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined (Line C)	38.46%

1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year (Line A *Col 2)	Tax Shield From Depreciation (Line C *Col 3)	O&M Cost (Line B)	O&M Tax Shield (Line C *Col 5)	Cash Outflow (Line A in Yr 1; Line B in Yrs 2-16)	Cash Outflow After Tax Shields (Col 7-(Col 6+Col 4))
1	0.000%	$0	$0	$0	$0	$614,487	$614,487
2	10.000%	$61,449	$23,630	$58,710	$22,577	$58,710	$12,503
3	9.643%	$59,254	$22,786	$58,710	$22,577	$58,710	$13,347
4	9.272%	$56,975	$21,910	$58,710	$22,577	$58,710	$14,223
5	8.886%	$54,601	$20,997	$58,710	$22,577	$58,710	$15,136
6	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
7	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
8	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
9	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
10	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
11	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
12	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
13	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
14	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
15	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
16	5.655%	$34,746	$13,362	$58,710	$22,577	$58,710	$22,771
Sum	100.00%	$614,487	$236,301	$880,650	$338,654	$1,495,137	$920,182
Present Value[a]		$396,120	$152,328	$534,726	$205,629	$1,149,213	$791,256

Present Value of Incremental Costs (Present Value of Col 8):	$791,256
Annualized Cost [a]:	$83,761

Note: Spreadsheet assumes that a modified accelerated cost recovery system (MACRS) is used to depreciate capital expenditures (see text).
[a] See Figure 4-2 for formulas.

Source: See Appendix A.

The *discount rate*, which reflects the costs of capital for pharmaceutical facilities and is used to calculate the present value of the cash flows, is based on the real cost of capital of 7 percent recommended by OMB.[6]

The final model parameters are the federal and average state *tax rates*, which are used in determining each facility's tax benefit or tax shield. A facility is allowed to reduce its taxable income by the amount spent on incremental O&M costs and by the depreciable portion of its capital equipment.[7] The tax rate used in the model is the marginal federal tax rate of 34% and the average state corporate income tax rate (see Appendix A). The average state tax rate is used in the cost annualization model because it can be unclear which state tax rates apply to a given facility's revenues. For example, a facility located in one state might be owned by a firm whose corporate headquarters is located in a second state and whose corporate holding company is located in a third.

4.2.2.3 The Cost Annualization Model Structure and Outputs

Two assumptions were made in annualizing compliance costs. The first assumption is that the facility owners will be using the Modified Accelerated Cost Recovery System (MACRS) to depreciate capital investments, which reduces the effective cost to the facility of purchasing and operating the pollution control equipment. The second is that a 1-year delay occurs between the purchase of pollution control equipment and its operation. The details of these assumptions and their impact on the results of the MACRS cost annualization model are presented in Appendix A.

In Table 4-2, the spreadsheet contains numbered columns in which the costs of the investment to the facility are calculated. The first column lists each year of the equipment's life span, from its

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[6] OMB, 1996. *Economic Analysis of Federal Regulations under Executive Order 12866.* January 11.

[7] Commerce Clearinghouse, Inc., 1995. *U.S. Master Tax Guide.* p 314.

installation through its 15-year depreciable lifetime.[8] Column 2 represents the portion of capital costs that can be written off or depreciated each year; these rates are based on MACRS, as shown in Appendix B. By multiplying these rates by the total capital cost, EPA calculates the annual amount the facility can depreciate (Column 3). These depreciable amounts are used by the firm to offset annual taxable income. Column 4 shows the tax benefit provided by the depreciation expense, (i.e., the overall tax rate times the depreciation amount for the year).

Column 5 of Table 4-2 shows the annual O&M expense. These costs are constant, except in Year 1 when no O&M costs are incurred because the equipment is not in service in this year. Column 6 shows the tax shield or benefit provided from expensing the O&M costs. Column 7 lists the facility's total expenses associated with the additional pollution control equipment: EPA assumes that capital costs are incurred during the first year when the equipment is installed. The O&M expense is added to capital costs for all years except Year 1. Column 8 lists the annual cash outflow minus the tax shields from the O&M expenses and depreciation because the facility will recoup these costs as a result of reduced income taxes.

Once the yearly cost to the facility has been determined, the yearly cost is transformed into a constant cost stream. The bottom line in Column 8 represents the present value of the costs over the equipment's life span. The annualized cost is calculated as the 16-year annuity (15 years plus one year) that has the same present value as the bottom line in Column 8 of Table 4-2. The annualized cost represents the annual payment required to finance the capital outlay and pay for O&M after tax shields. In essence, paying the annualized cost every year and paying the amounts listed in Column 8 for each year are equivalent. In this example, the capital investment of $614 thousand and annual O&M cost of $59 thousand (1990 dollars) result in an annualized posttax cost of $101 thousand.[9] Figure 4-2 presents the equations used to calculate present value and annual cost.

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[8] An asset's depreciable life can differ from its actual life. The pollution control equipment considered in this analysis is in the 15-year property class; however, the actual life could extend to 25 years. EPA's estimate of annualized costs is conservatively high as long as the equipment does not have to be replaced in its entirety (costs for replacement pumps and other equipment needed for maintenance have been included in O&M) in less than 16 years (see Appendix A).

[9] Note that the annualized cost can be determined in two ways. The first way is to calculate the annualized cost as the difference between the annuity value of the cash flows (Column 7) and the tax shields (Columns 4 and 6). The second way is to calculate the annuity value of the cash flows after tax shields (Column 8). Both methods yield the same value.

$$\text{NET PRESENT VALUE} = v_1 + \sum_{i=2}^{n} \frac{v_1}{(1 + \text{int})^{i-1}}$$

where:

$v_1 ... v_a$	=	series of cash flows
int	=	interest rate
n	=	number of cash flow periods
i	=	current iteration

$$\text{ANNUALIZED PAYMENT} = \text{principle} \times \frac{\text{int}}{1 - (\text{int} + 1)^{-n}}$$

where:

int	=	periodic interest rate
n	=	term

Figure 4-2. Calculations used to compute present value.

The present value of the cost for incremental pollution control is used in the facility analysis as a proxy for the change in facility earnings. The present value of O&M plus the present value of deprecation are used in Section Six as the change in earnings before interest and taxes (EBIT), which is needed to estimate the impacts on firms (Section Five). Results of the calculation of aggregate compliance costs are presented below in Section 4.2.

4.3 TOTAL ANNUALIZED COMPLIANCE COSTS

EPA calculates total annualized compliance costs by aggregating the annualized compliance costs for all affected facilities, based on the output of the cost annualization model. Table 4-3 presents the results of this cost aggregation by regulatory option. Impacts on firms and facilities, which are discussed in other sections of this report, are calculated on the basis of these posttax costs (i.e., the costs as perceived by the affected firms and facilities after taxes are paid).

As Table 4-3 shows, costs of all options range from $0.2 million to $23.4 million, with the selected options ranging from $0.7 million (for B/D directs; cost of BPT only) to $23.4 million for A/C indirects. Each subcategory also has a no-action option. These no-action options are not presented here, because they are associated with zero costs. Average costs per facility range from $31,000 to $266,000 among the selected options. Total costs of all selected options are $32.0 million.

4.4 COSTS OF THE PHARMACEUTICAL EFFLUENT GUIDELINES WITH MACT STANDARDS COSTS INCLUDED

Table 4-4 presents the sum of the selected options, as well as compliance costs for MACT standards requirements (which are annualized using the same model and assumptions described in Section 4.3). As the table shows, the total cost of the selected options for the Final Pharmaceutical Effluent Guidelines is $32.0 million ($1990). With MACT standards wastewater emission control costs included (see Section Two and Appendix B), the water-related cost of the two rules is $37.8 million ($1990). Total cost of both rules together (for facilities in the effluent guidelines analysis only) is $58.3 million ($1990). Total cost of both

Table 4-3

Annualized Posttax Costs of Compliance with Final Pharmaceutical Industry Effluent Guidelines (1990 dollars)

Option *	Capital Costs	O&M Costs	Annualized Compliance Costs	Facilities Incurring Costs **	Average Costs per Facility ***
Direct Discharge					
BPT-A/C	$2,422,402	$1,825,253	$1,275,930	24	$53,164
BPT-B/D	$1,785,772	$966,864	$715,893	14	$51,135
BAT-A/C	$5,569,135	$2,423,726	$1,881,579	24	$78,399
Indirect Discharge					
PSES-A/C	$80,864,749	$28,597,244	$23,407,105	88	$265,990
PSES-B/D	$22,067,126	$5,010,342	$4,729,914	153	$30,914
All Facilities					
Total Selected Options	$112,709,184	$38,823,429	$32,010,421	279	$114,733

* All subcategories have a no-action option; the no-action options are not presented here, since costs for those options are zero.
** The total number of facilities incurring costs includes all facilities except for seven zero discharge facilities.
*** Over number of facilities that incur costs.

Table 4-4

Cost of Selected Options and MACT Standards Costs
(1990 dollars)

Cost Category	Capital Costs	O&M Costs	Annualized Compliance Costs	Facilities Incurring Costs *	Average Costs per Facility **
Selected effluent guidelines option costs	$112,709,184	$38,823,429	$32,010,421	279	$114,733
MACT standards costs (wastewater emission controls)	$30,907,772	$5,644,605	$5,810,120	20	$290,506
Total MACT for effluent guidelines analysis	$102,822,547	$30,535,434	$26,305,357	71	$370,498
Total MACT standards costs, all facilities	$120,263,588	$36,007,268	$30,940,806	NA	NA
Selected effluent guidelines options and MACT standards wastewater costs	$143,616,956	$44,468,034	$37,820,541	279	$135,557
Selected effluent guidelines options and MACT standards total costs (effluent guidelines facilities only)	$215,531,731	$69,358,862	$58,315,778	279	$209,017
Selected effluent guidelines options and MACT standards total costs (all facilities) ***	$232,972,772	$74,830,697	$62,951,227	NA	NA

* The total number of facilities incurring costs includes all facilities except for seven zero discharge facilities.
** Over facilities that incur costs.
*** Total includes MACT standards costs for some facilities not in the effluent guidelines analysis; the average is calculated only ovr facilities in the effluent guidelines analysis.

rules, including MACT standards costs for facilities not covered by the Final Pharmaceutical Industry Effluent Guidelines, is $63.0 million ($1990).

SECTION FIVE

ANALYSIS OF FACILITY-LEVEL IMPACTS

This section presents the facility-level economic impact methodology and reports the results of the facility economic impact analysis (closure analysis). This analysis, described in Section 5.1, uses output from the cost annualization model (discussed in Section Four) to predict facility closures. Section 5.2 summarizes the results of the analysis in terms of the number of facility closures that occur prior to regulatory compliance (baseline closures) and presents the number of facility closures that result from regulatory compliance (incremental closures). Section 5.3 discusses impacts on new sources.

This section discusses the impacts on 206 facilities.[1] There are 286 facilities in the survey universe. Four facilities provided insufficient data to measure impacts. Of the remaining 282 facilities with sufficient data, 148 facilities are not directly considered by the facility closure model. These 148 facilities comprise two groups: certifying facilities and single-facility firms. These latter two groups and the reasons they are not directly considered by the model are described below.

EPA exempted facilities from providing facility-level data if the company owners certified that the regulation would have no economic impact on the facility. Seventy-two facilities (weighted) certified no economic impact on the facility (i.e., the rulemaking will be economically achievable for the company and its certified facilities). The 72 certifying facilities, are placed automatically in the "no-closure" category by the facility closure model. Another 76 facilities in the survey universe indicated that their owner firm and the facility are the same entity (i.e., the firm owns only one facility). In these cases, the firm-level analysis in Section Six was determined to be the appropriate level at which to evaluate impacts on these facilities. This approach avoids double counting of impacts at both the firm level and facility level for these single-facility firms. Results of the analysis show impacts relative to the 134 "nonindependent" facilities that are owned by multifacility firms and that provided sufficient survey data. These facilities are the primary focus of the facility-level analysis. The 72 certifiers are added to the no-impact results for a total of 206 facilities discussed in this analysis.

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[1] Options for new sources are evaluated later in Section 5.3. See Section Four for a description of all regulatory options.

5.1 FACILITY IMPACT MODEL

In this analysis, EPA estimates facility impacts by evaluating the impact of compliance costs on a facility's earnings.[2] To do this, EPA compares each facility's average annual precompliance, posttax earnings with its annualized pollution control costs.

The present value of earnings represents the value in current dollars of the expected earnings that the facility can generate over a specified period (in this case 16 years; see below). If the present value of future posttax earnings is expected to be less than or equal to zero, EPA assumes that the facility would cease operation, as it would no longer be a profitable venture.

Posttax earnings are used instead of pretax earnings because it is not appropriate to compare a pretax number (earnings) to a posttax number (compliance cost). There are a number of highly conservative assumptions that are embodied in this approach, however. First, posttax earnings can be substantially smaller than posttax cash flow since posttax cash flow is defined as posttax earnings plus depreciation. Using posttax earnings could therefore overstate actual baseline closures, possibly leading to unreliable estimates of postcompliance closures. However, to ensure that postcompliance closures are not understated, EPA does investigate impact on facilities, even if they are estimated to close in the baseline, by investigating impacts at the firm level as well (see discussion in Section 5.1.2). If the firm cannot install and operate pollution control equipment at all of its facilities, including those estimated to close in the baseline, without being threatened by bankruptcy, then impacts on the firm and its facilities are identified. Second, compliance costs, as calculated in Section Four, are really calculated based on cash outflows. Because the present value of compliance costs is calculated on the basis of the assumption that capital costs are a cash outflow in Year 1, the present value of compliance costs is higher than it would have been had the present value been calculated on the basis of O&M plus depreciation costs (which occur in small increments over 16 years); i.e., the change in posttax earnings. To be conservative and to avoid the criticism that a change in posttax earnings does not account for capitalization costs, EPA uses the present value of compliance costs calculated as described in Section Four to compare to posttax earnings. This approach creates a conservative measure of impact that, nevertheless, has no true basis in general accounting practices.

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[2] Ideally, the impact of compliance costs would be judged against a facility's cash flow, but EPA did not have access to data that would have allowed the Agency to determine cash flow.

The methodology used to determine closures is somewhat of a departure from other EAs and Economic Impact Analyses (EIAs) for effluent limitations guidelines and standards in which salvage value (the residual value of the facility at liquidation) was considered to play a role in an assessment of the financial viability of a facility (i.e., the decision to liquidate would be based on whether the estimated salvage value exceeded the estimated present value of cash flow). For a number of reasons, EPA believes that using salvage value in this way for this industry could overstate baseline closures, leading to an unreliable estimate of postcompliance closures. First, the appropriate use of salvage value is in comparison to cash flow. Without knowing depreciation, EPA cannot construct cash flow. Using salvage value without considering depreciation could seriously overstate baseline closures. Second, facilities in this industry are not necessarily profit centers. They may be transferring product at cost (i.e., operating cost only) or are otherwise not expected to be self-supporting. Third, the computation of salvage value has always been difficult, and many errors can arise because of the numerous assumptions that must be made. Fourth, liquidation costs also must be weighed against salvage value, and these costs can be even more difficult to estimate than salvage value, given the lack of the site-specific data needed to estimate the costs. Using salvage value without considering liquidation costs would also overstate baseline closures. Finally, one commenter also stated that using salvage value overstated baseline closures and was concerned that postcompliance results might thereby be understated. EPA believes the results of the closure analysis are more accurate without the use of salvage value, both in the baseline and postcompliance. For these reasons, EPA has changed the methodology and does not use salvage value in determining closure.

Section 5.1.1 describes the calculations used to determine the present value of future posttax earnings for a facility, and Section 5.1.2 discusses how closure results are evaluated using the facility impact model.

5.1.1 Estimating the Present Value of Forecasted Earnings

As stated previously, the present value of each facility's posttax earnings is equal to its future stream of posttax earnings in current dollars. The impact methodology uses survey data on earnings to estimate future earnings and then applies a discount rate to derive the present value of future earnings. The components of this analysis include: (1) estimating current posttax earnings; (2) estimating the present value of future posttax earnings, which involves projecting earnings during the relevant time frame and discounting

them to the present; and (3) evaluating impacts (adjusting the regulatory baseline for baseline closures and incorporating the incremental costs of regulation).

5.1.1.1 Estimating Current Earnings

EPA estimated current earnings based on value of shipments of pharmaceutical and nonpharmaceutical items minus the costs of operations (which include some measure of depreciation for buildings and possibly equipment as well) as reported in the Section 308 Survey. This measure is thus an approximation of earnings before interest and taxes. Respondents generally provided three years of data (1988, 1989, 1990), which were adjusted to 1990 dollars using the change in CPI for SIC 283 over those years. EPA then averaged the three years of data to create base year earnings.[3] EPA then adjusted earnings by the marginal tax rate of the owner firm to create an estimate of current annual posttax earnings.

5.1.1.2 Estimating the Present Value of Future Earnings

Current annual posttax earnings can be used to estimate the present value of future earnings by setting a time frame for the analysis (16 years, as discussed in Section Four), defining any trends or cycles that the affected industry's earnings might follow, and discounting the earnings projected over the time frame to the present time.[4]

EPA has determined that a slightly rising earnings forecast over the defined 16-year period (see Section Four) best fits the data provided in the Section 308 Survey as well as that from other sources (see Section Three). In general, the surveyed facilities in the postcompliance facility closure analysis discussed in Section 5.2.2 had a median increase in posttax earnings of 4.2 percent between 1988 and 1990. Between 1988 and 1989, the surveyed facilities showed a small real decline in earnings (median of -3.4 percent).

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[3] EPA made one exception for a facility that came online in 1990. EPA used the 1990 data by itself, rather than averaging the data with the previous years' data (which were zeros).

[4] The earnings period and the cost annualization period are the same to keep the annualized costs comparable to earnings. Otherwise either earnings or annualized costs might be overstated relative to the other.

Growth surged, however, between 1989 and 1990 (median of 6.8 percent) to more than make up for the previous decline. Note that shipments also increased 4.5 percent over those years in SIC 283 (see Table 3-4 in Section Three). To be conservative, EPA models growth in the industry as flat (thus avoiding the assumption that the industry can "grow" its way out of financial impacts). Because general industry information indicates that this industry is neither cyclical nor declining (see Section Three), EPA expects the flat earnings growth projection to yield a reasonable estimate of the present value of future earnings.

To represent this flat earnings growth, EPA used base-year earnings (see Section 5.1.1.1) in constant 1990 dollars and assumed they would remain constant over the 16-year period of analysis, using a real (not a nominal) discount rate. The same cost of capital factor (discount rate) used in the cost annualization model is used to discount earnings.

5.1.2 Evaluating Impacts

Establishing the Regulatory Baseline

OMB directs agencies to develop a regulatory baseline against which to judge impacts. OMB's guidance states:

> The benefits and costs of each alternative must be measured against a baseline. The baseline should be the best assessment of the way the world would look absent the proposed regulation. That assessment may consider a wide range of factors, including the likely evolution of the market...[5]

EPA must assess the impacts of the Final Pharmaceutical Industry Effluent Guidelines against a baseline that is the Agency's best assessment of the way the world would look without the regulation. In this analysis, EPA has established three baselines. Baseline 1 is a baseline in which EPA has considered neither effluent guideline compliance costs nor MACT standards compliance costs for facilities that are subject both to MACT standards costs and effluent guidelines costs. Baseline 2 adjusts posttax earnings to reflect the posttax change in earnings that will occur given the costs of MACT standards that are associated with

[5] OMB,1996. *Economic Analysis of Federal Regulations under Executive Order 12886*. January 11.

wastewater emission controls. Baseline 3 further adjusts Baseline 2 posttax earnings to reflect the change in earnings associated with the costs of total MACT standards costs. See Section Two and Appendix B of this EA for more details on MACT standards requirements and costs.

Impacts in this and subsequent sections will be presented as incremental to all three baselines. EPA presents impacts this way because the two final rules (MACT standards and the Final Pharmaceutical Industry Effluent Guidelines) will be signed nearly concurrently. The three baselines allow EPA to properly assess the impact of this rulemaking both individually and with MACT standards requirements in place.

Under all three baselines, if a facility's present value of posttax earnings is less than or equal to zero over the 16-year time frame, EPA's best estimate is that this facility is a baseline closure independent of the impact of this proposed rule. Although it is possible that a facility estimated to be a baseline closure might remain open, the converse also might be true—a facility projected to remain open until it is subject to the rule might actually close independently of the rule. Either result might be likely. If EPA were to assume that all facilities that are estimated to close in the baseline were actually postcompliance closures, this would seriously overstate impacts. To avoid either seriously overstating or understating impacts, EPA has chosen to estimate postcompliance closures by counting facilities that are projected to close solely due to the effects of the Final Pharmaceutical Industry Effluent Guidelines and/or MACT standards rule.

Furthermore, EPA assesses impacts on nonindependent facilities (facilities that are owned by multifacility firms) that are estimated to close in the baseline by investigating whether the firm can continue to support the facility in the firm failure analysis. The nonindependent facilities with negative or zero operating earnings as reported in the Section 308 Survey are assumed likely to be subsidized by their owners, since they are not supporting themselves currently. If they are being subsidized in the baseline, then EPA can assume they will continue to be subsidized postcompliance, as long as the firm can afford to continue to support all of its facilities postcompliance (which is analyzed in Section Six).[6]

For all of these reasons, EPA creates a regulatory baseline by first evaluating the *current* baseline (represented by the data collected in the Section 308 Survey) and determining which facilities are likely to

[6] The analysis in Section Six shows that all multifacility firms with facilities that close in the baseline can install and operate pollution control without major financial impacts.

close regardless of regulatory requirements, as directed by OMB Guidance. The facilities that are not expected to close are then used to establish the *regulatory* (as opposed to the current) baseline.[7] This regulatory baseline is the one against which incremental impacts in the postcompliance closure analysis are measured.

In analysis of the *current* baseline, EPA uses the model as described above to calculate the present value of the earnings stream over the 16-year time frame. If a facility's present value of posttax earnings (current baseline posttax earnings), as reported in the survey, is less than or equal to zero, EPA classifies that facility as a "baseline closure." These "closure" facilities are eliminated from the regulatory baseline used in the subsequent, postcompliance closure analysis either because (1) such closures are expected to occur regardless of the Final Pharmaceutical Industry Effluent Guidelines, and therefore cannot be attributed to increased regulatory costs, or (2) because the closure analysis is irrelevant, and the appropriate level of analysis is at the firm level (for nonindependent facilities that are not self-supporting). When baseline closures are removed, the current baseline becomes the regulatory Baseline 1.

EPA adjusts Baseline 1 to create Baseline 2 by incorporating the change in posttax earnings associated with the MACT standards wastewater emission control costs. The change in posttax earnings is generated by the cost annualization model and is used as described below for incorporating compliance costs of the Final Pharmaceutical Industry Effluent Guidelines. The same procedure is also used to incorporate the change posttax earnings associated with Total MACT standards costs to create Baseline 3. Baseline closures are assessed for all three baselines.[8]

Incorporating Compliance Costs

For the postcompliance closure analysis, EPA calculates the impacts of the Final Pharmaceutical Industry Effluent Guidelines costs on earnings using the facility-specific posttax present value costs for each regulatory option (see Section Four) in comparison to the three regulatory baselines. The present value of

[7] In this case, three regulatory baselines are created, as discussed earlier in this section.

[8] Note that any baseline closures attributed to Baseline 2 or Baseline 3 are attributed to the costs of complying with MACT standards requirements.

compliance costs is then subtracted from the present value of Baseline 1, 2, and 3 posttax earnings to compute each facility's postcompliance posttax earnings under the three regulatory baselines.[9]

Note that this analysis assumes that no costs will be passed through to consumers, which is considered extremely conservative in this analysis of industry impacts (i.e., tends to overstate impacts on industry). However, when impacts on consumers are estimated in Section Eight, EPA assumes that *all* costs are passed through to consumers. Neither assumption is realistic, but provides upper bound estimates of impacts on both industry and consumers.

After computing postcompliance earnings, the model notes for which facilities the present value of earnings are less than or equal to zero and classifies these facilities as postcompliance closures attributable to the Final Pharmaceutical Industry Effluent Guidelines under all three baselines. The number of estimated closures is recorded for all nonindependent and certifying facilities.

5.2 RESULTS

5.2.1 Baseline Closures

Table 5-1 presents the results of the analyses used to identify baseline closures under the three baselines. Under Baseline 1, 18 facilities out of 206 nonindependent and certifying facilities (8.7 percent) are estimated to close regardless of regulatory requirements.[10] All of these facilities are assessed further in the firm analysis to determine whether their firms can afford to install and operate pollution control equipment, on the assumption that these facilities might not be expected to be self-supporting. No additional facilities close under Baseline 2 or 3 (thus MACT standards costs by themselves will not have a major impact on the facilities analyzed in this EA).

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[9]As noted earlier, because the cost annualization model really computes annualized and present value cost on a cash flow-type basis, the change in earnings is slightly overstated.

[10] A total of 206 weighted facilities remain in the analysis after excluding 4 facilities with insufficient data and 76 single-facility firms.

Table 5-1

Baseline Facility Closures

Facility Type	Total Number of Facilities	Baseline 1 Closures		Baseline 2 Closures		Baseline 3 Closures	
		Number	% of Total	Number	% of Total	Number	% of Total
Direct Discharge							
A/C	20	1	0.5%	1	0.5%	1	0.5%
B/D	13	1	0.5%	1	0.5%	1	0.5%
Indirect Discharge							
A/C	64	3	1.5%	3	1.5%	3	1.5%
B/D	105	13	6.3%	13	6.3%	13	6.3%
Zero Discharge							
A/C	2	0	0.0%	0	0.0%	0	0.0%
B/D	2	0	0.0%	0	0.0%	0	0.0%
All Facilities							
Total *	206	18	8.7%	18	8.7%	18	8.7%

* Note: Total does not include four facilities with insufficient data.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

5.2.2 Postcompliance Closures

Under Baselines 1 and 2, for the Final Pharmaceutical Industry Effluent Guidelines options, no facilities are expected to close (see Table 5-2). Only in Baseline 3 (with all MACT standards costs considered) does one facility (an A/C indirect discharger) close under the selected options. Note that these results apply only to facilities owned by multifacility firms. The likelihood that single-facility firms might fail and close postcompliance is investigated in Section Six.

5.3 IMPACTS ON NEW SOURCES

The selected options for new sources are equivalent to the selected options for existing sources. Because the costs for designing pollution control technologies are generally no more expensive than and are usually less expensive than retrofitting pollution control technologies, costs for new facilities will be no more expensive than costs for existing facilities. Because EPA has shown that the requirements for existing sources are economically achievable, they should be economically achievable for new sources. Furthermore, since the requirements for new sources will not be more expensive than those for existing sources, the rule will not pose a barrier to entry for new sources.

In response to proposal comments, EPA investigated whether impacts from the effluent guidelines rule (with and without MACT standards costs included) might contribute to firms locating new facilities in foreign countries. EPA devised a methodology to compare to the compliance costs of the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule to typical startup costs for new facilities. Several facilities in the Section 308 survey started up during the 1988-1990 time frame. For these very new facilities, EPA assumed that their total assets reported in the survey would be a reasonable proxy for the capital necessary to build and outfit a new facility. Although some startup capital is used to pay for intangibles or other nonasset items, total assets among new facilities should be a conservatively low estimate of startup capital. EPA then compared compliance costs to total assets at each newer facility. EPA found the median percentage of the capital costs of compliance (including MACT standards costs) to build a new facility would be negligible (0.21 percent of startup costs at newer surveyed facilities). Thus compliance costs

Table 5-2

Postcompliance Facility Closures

Options	Baseline 1			Baseline 2			Baseline 3		
	Total Number of Facilities	Postcompliance Closures		Total Number of Facilities	Postcompliance Closures		Total Number of Facilities	Postcompliance Closures	
		Number	% of Total		Number	% of Total		Number	% of Total
Direct Discharge									
BAT-A/C (with BPT)	19	0	0.0%	19	0	0.0%	19	0	0.0%
BAT-B/D (with BPT)	12	0	0.0%	12	0	0.0%	12	0	0.0%
Indirect Discharge									
PSES-A/C	61	0	0.0%	61	0	0.0%	61	1	0.5%
PSES-B/D	92	0	0.0%	92	0	0.0%	92	0	0.0%
All Facilities									
Total Selected Options *	188	0	0.0%	188	0	0.0%	188	1	0.5%

* Total includes five nondischarging facilities; does not include four facilities with insufficient data.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

associated with Final Pharmaceutical Industry Effluent Guidelines and/or the MACT standards rule are unlikely to be a major impetus to locating new facilities outside the United States.

SECTION SIX

ANALYSIS OF FIRM-LEVEL IMPACTS

The firm-level analysis evaluates the effects of regulatory compliance on firms owning one or more affected pharmaceutical facilities. It also serves to identify impacts not captured in the facility analysis. For example, some firms might be too weak financially to undertake the investment in the required effluent treatment, even though the investment might seem financially feasible at the facility level. Such circumstances can exist, in particular, at firms owning more than one facility subject to regulation. Given the range of possible firm-level impacts, the firm-level analysis is an important component of this EA.

EPA determined that 190 firms are potentially affected by the Final Pharmaceutical Industry Effluent Guidelines, of which 36 are considered certifying firms—that is, they certified their surveyed facilities as incurring no impacts under the Final Pharmaceutical Industry Effluent Guidelines. Certifying firms are assigned a no impact status by the firm-level model. Three firms had insufficient data against which to judge impacts, thus this analysis investigates impacts on 187 firms.

To evaluate precompliance conditions at and postcompliance impacts on noncertifying firms, EPA divided the firms into two categories—single-facility firms and multifacility firms (see Section Five).

A total of 76 firms classified themselves as single-facility firms.[1] These firms operate as independent entities, although, in some cases, single-facility firms can have an ultimate parent company. As independent entities, these firms maintain balance sheets and income statements and pay corporate taxes on their own earnings. Single-facility firms also are generally smaller than multifacility firms in terms of revenues, production, and employment. Of these firms, 66 meet the definition of small under Small Business Administration (SBA) definition (fewer than 750 employees). Section Nine discusses the combined impacts of closures and failures on small firms in the pharmaceutical industry

[1]As noted in Section Five, single-facility firms are both firms and facilities. EPA evaluates impacts on these entities on the firm level in this section rather than on a facility level in Section Five.

In addition to the 76 single-facility firms, EPA estimated that there are 114 multifacility firms. These firms own and operate more than one facility and have at least one pharmaceutical facility.[2] In addition, they maintain financial records for all their facilities at the firm level and typically pay corporate taxes at the firm level for all owned facilities. As noted above (and as shown in Section Three), multifacility firms tend to be substantially larger than single-facility firms although 80 are classified as small under SBA definitions.[3,4]

The basic core of the firm-level analysis, both for single-facility and multifacility firms, is the Altman Z-score analysis, a ratio analysis that employs several indicators of financial viability to assess firm-level precompliance conditions and postcompliance impacts. Section 6.1 presents an overview of this ratio analysis methodology. Section 6.2 discusses the Altman Z-score model as it applies to the pharmaceutical industry. Section 6.3 summarizes the results of the firm-level analysis in terms of the number of firms that face bankruptcy prior to regulatory compliance (baseline bankruptcies) and the number of firms that are estimated to experience bankruptcy as a result of additional regulatory compliance costs associated with the Final Pharmaceutical Industry Effluent Guidelines (incremental bankruptcies). It also discusses the number of firms that, while considered financially healthy in the baseline, slip from the financially healthy category into an indeterminate category in the postcompliance analysis (this is considered an impact short of bankruptcy). All of these results occur under the assumption that no costs can be passed through to customers and thus are likely to be an upper bound of potential impacts to industry from the rule.

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[2] EPA assumes that all multifacility firms are captured by the Section 308 Survey. Where a multifacility firm owns a facility with a statistical weight of 2, EPA assumes that the firm owns two such facilities and assigns compliance costs on that basis. All facilities were either censused (and have a weight of 1) or were sampled (and have a weight of approximately 2). Three multifacility firms were not analyzed due to insufficient data.

[3] Impacts on parent companies (i.e., owners of the owner companies) are not analyzed in this EA because the impacts of a given facility closure or major facility-level capital investment become more dilute as assets increase at higher levels in the corporate hierarchy. Thus EPA's analysis assumes that the impacts fall on the most vulnerable firms. Had EPA assumed that the firms in the analysis could be "bailed out" by their parent companies, impacts would most likely have appeared less. For most of the 76 single-facility firms, however, analysis at the facility level, firm level, and corporate parent level coincide.

[4] The large number of multifacility firms classified as small occurs because employment numbers were estimated for many of these firms, based primarily on the employment figures *for their surveyed facilities only*. Therefore these estimates of employment are considered lower bound in most cases.

6.1 RATIO ANALYSIS METHODOLOGY

Ratio analyses are conducted from the perspective of creditors and equity investors who would finance a company's treatment system investment. To attract financing for a treatment system, a company must demonstrate financial strength both before and, on a projected basis, after the treatment system has been purchased and installed. The ratio analysis undertaken in this section simulates the analysis an investor and/or creditor would be likely to employ in deciding whether to finance a treatment system or make any other investment in the firm.

The baseline ratio analysis evaluates the company's financial viability before the investment, and the postcompliance analysis predicts the company's financial condition subsequent to the investment. The baseline analysis identifies companies in extremely weak financial condition, independent of pending regulatory actions. Such companies are at risk of financial failure even without the additional cost of the regulation. Firms that are projected to fail in the baseline analysis are excluded from the postcompliance analysis. This development of a regulatory baseline is consistent with OMB guidance, as discussed in Section Five.[5] Again, as in Section Five, EPA has developed three baselines. Baseline 1 represents the industry prior to either the MACT standards rule or the Final Pharmaceutical Industry Effluent Guidelines, Baseline 2 incorporates MACT standards costs associated with wastewater emission controls into the affected firms' baseline finances, and Baseline 3 adds total MACT standards costs into these finances. The methodology for incorporating MACT standards costs into the baseline is presented in Section 6.2.

The postcompliance analysis identifies companies for which regulatory compliance poses a threat to financial viability, although they are otherwise financially sound. Such companies could be weakened by the costs of meeting the requirements of the rule. These companies are characterized as experiencing a larger impact from the Final Pharmaceutical Industry Effluent Guidelines than the majority of pharmaceutical firms. Postcompliance impacts are measured incrementally from all three regulatory baselines.

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[5] OMB, 1996. *Economic Analysis of Federal Regulations under Executive Order 12866.* January 11.

For the pharmaceutical industry, a ratio analysis based on the Altman Z-score is used to characterize the baseline and postregulatory financial conditions of potentially affected firms. This method is described in more detail below.

The Altman Z-score, originally developed in the late 1960s for manufacturing firms, is a multidiscriminant analysis (MDA) used to assess bankruptcy potential.[6,7] Over the years, the Altman Z-score model has gained acceptance among financial institutions[8] and, more recently, has been used by EPA in the economic and regulatory impact analyses for centralized waste treaters, the pulp and paper industry, transportation equipment cleaning, and industrial laundries. Altman's Z-score model analyzes a number of financial ratios simultaneously to arrive at a single number to predict the overall financial health of a particular firm. The advantage of the Altman Z-score model over traditional ratio analysis is its simultaneous financial consideration of liquidity, asset management, debt management, profitability, and market value. It addresses the problem of how to interpret a series of financial ratios when some financial ratios look "good" while other ratios look "bad."[9] The Altman Z-function is given in Equation 1:

$$Z = 1.2X_1 + 1.4X_2 + 3.3X_3 + 0.6X_4 + 1.0X_5 \quad \textbf{(1)}$$

where,

[6] Multidiscriminant analysis is a statistical procedure similar to regression analysis. It is used primarily to classify or make predictions in cases where the dependent variable is qualitative. In this case, the dependent variable would be "financially stable" or "financially unstable."

[7] Altman, Edward, 1993. *Corporate Financial Distress and Bankruptcy*. New York: John Wiley and Sons.

[8] See for example, Altman, 1993, *Ibid.;* Brealy, Richard A., and Stewart C. Meyers, 1996. *Principles of Corporate Finance*, McGraw Hill Companies, Inc.; and Brigham, E.F., and L.C. Gapenski, 1997. *Financial Management Theory and Practice.* Chicago: The Dryden Press, 8th edition, pp. 1064-1066.

[9] Brigham, Eugene F., and Louis C. Gapenski, 1997. *Ibid.*

$$Z = Overall\ Index$$

$$X_1 = \frac{Working\ Capital}{Total\ Assets}$$

$$X_2 = \frac{Retained\ Earnings}{Total\ Assets}$$

$$X_3 = \frac{Earnings\ Before\ Interest\ and\ Taxes}{Total\ Assets}$$

$$X_4 = \frac{Market\ Value\ of\ Equity}{Book\ Value\ of\ Total\ Liabilities}$$

$$X_5 = \frac{Sales}{Total\ Assets}$$

Each of the above ratios is further defined below.

- ***Working Capital to Total Assets*** is a liquidity ratio which measures a firm's net liquid assets relative to total capitalization.[10]

- ***Retained Earnings to Total Assets*** indicates the total amount of reinvested earnings and/or losses associated with a firm over its entire life, relative to total capitalization.

- ***EBIT to Total Assets*** measures the productivity of a firm's assets. Earnings are total firm revenues minus total firm costs (including general and administrative costs and depreciation).

- ***Market Value of Equity to Total Liabilities*** is a solvency ratio that measures the firm's total indebtedness to the capital invested by the stockholders. High debt levels can indicate high levels of risk.

- ***Sales to Total Assets*** is another measure of the productivity of a firm's assets.

The Section 308 Survey was not designed originally to perform an Altman Z analysis and lacked data on retained earnings and market value of equity (a major issue only for public firms since retained earnings

[10] Working capital is current assets minus current liabilities and is a measure of available cash on hand.

typically are less than owner equity, and market value often exceeds book value by a wide margin). EPA therefore used financial data from annual reports, 10-K forms, and accounting reports that were submitted as a part of the Section 308 Survey, where available, to obtain these data. EPA also obtained data from SEC submittals for approximately 40 firms identified as "sensitive" in the analysis.[11]

In a later work, Altman developed two modified versions of this original model for use in evaluating privately held firms (Z′-score) and firms within a service industry (Z″-score).[12] In the original model, the market value component (X_4) uses stock price data; consequently, the Altman Z-score is only applicable to firms with publicly traded stock. The Z′-score model substitutes the book value of equity (owner equity) for the market value in X_4 and thus can be used to evaluate privately and publicly held firms on an equal basis.

Because the pharmaceutical industry includes both publicly and privately owned firms, the Agency has identified, to the extent possible, whether the firms are public or private. Where no information on whether a firm is public or private was available, EPA has assumed the firm is private (see footnote above). The Z′-score model for private firms is shown in equation 2.

$$Z' = 0.717X_1 + 0.847X_2 + 3.107X_3 + 0.42XX_4 + 0.998X_5 \quad \textbf{(2)}$$

where,

[11] These key firms were either (1) baseline or postcompliance failures when run as private firms, (2) baseline or postcompliance failures when run as public firms or (3) indeterminate (i.e., neither appearing as financially healthy or as a likely candidate for bankruptcy run either as a public or private firm), but only if compliance costs to revenues exceeded 0.1 percent under a worst-case cost scenario. For firms with no data (they did not submit supporting financial data, submitted financial data only for an ultimate parent firm, or could not be found in SEC submittals), EPA assumed the firm was private. This assumptions should not affect the outcome of this analysis, since the Agency also ran an analysis assuming these firms were public firms, using the assumption that retained earnings equaled one-third of owner equity and that market value equaled book value, with no change in outcome.

[12] Altman, Edward. 1993. *Op. cit.*

$$Z' = \text{Overall Index}$$

$$X_1 = \frac{\text{Working Capital}}{\text{Total Assets}}$$

$$X_2 = \frac{\text{Retained Earnings}}{\text{Total Assets}}$$

$$X_3 = \frac{\text{Earnings Before Interest and Taxes (EBIT)}}{\text{Total Assets}}$$

$$X_4 = \frac{\text{Book Value of Equity}}{\text{Total Liabilities}}$$

$$X_5 = \frac{\text{Sales}}{\text{Total Assets}}$$

Taken individually, each of the ratios given above (X_1 through X_5) using either equation is higher for firms in good financial condition and lower for firms in poor financial condition. Consequently, the greater a firm's bankruptcy potential, the lower its discriminant score. For public firms, an Altman Z-score below 1.81 indicates that bankruptcy is likely; a score above 2.67 indicates that bankruptcy is unlikely. Z-scores between 1.81 and 2.67 are indeterminate. Likewise for private firms an Altman Z′-score below 1.23 indicates that bankruptcy is likely and one above 2.90 indicates that bankruptcy is unlikely. A score of 1.23 to 2.90 is indeterminate.[14] EPA treats firms with indeterminate scores as financially viable but nevertheless undertakes a separate postcompliance analysis of firms that have baseline scores in the range indicating that bankruptcy is unlikely, but with postcompliance scores in the indeterminate range. These firms are considered to experience some financial impact short of bankruptcy.

[13] For this analysis, owner equity (which is total assets minus total liabilities) is used as a proxy for retained earnings for privately held firms. Owner equity includes retained earnings; it also can include paid-in capital, which is the dollar amount over par in stock value for publicly held firms and shares of preferred and common stock. For privately held firms, therefore, owner equity will equal retained earnings.

[14] Altman, 1993. *Op. cit.*

6.2 EVALUATING BASELINE AND POSTCOMPLIANCE RATIOS

6.2.1 Baseline Analysis

As discussed in Section Five, OMB requires EPA to establish a regulatory baseline. There are a number of firms in this analysis that are estimated to be likely to fail regardless of whether the rule is promulgated. As was done in Section Five for facilities closures, EPA divides vulnerable firms into those likeliest to fail in the baseline vs. those likeliest to fail postcompliance as a way to avoid either overcounting or undercounting impacts.

The Baseline 1 analysis uses the Altman Z-score or Z′-score model to separate financially healthy firms from those likely to fail regardless of whether the regulation is promulgated. To evaluate the baseline viability of the companies analyzed, the baseline Altman Z-score was calculated for each firm using Section 308 Survey data and data from other sources (e.g., 10K forms). Where sufficient data were available, 3-year average (1988-1990) financial ratios were calculated and used as the baseline ratios.[15]

Those firms with baseline scores below 1.81 (public) or 1.23 (private) are considered baseline failures and are removed from the analysis. All other firms (including those with scores in the indeterminate range) are included in the postcompliance analysis.

Baseline 2 is created by using MACT standards costs associated with wastewater emission controls to adjust baseline financials, similar to how effluent guideline compliance costs are used to adjust postcompliance financials, as discussed below in Section 6.2.2. Baseline 3 is created by using total MACT standards costs to adjust Baseline 1 financials.[16]

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[15] Data on assets, liabilities, owner equity, and EBIT from the Section 308 Survey were inflated by the CPI for SIC 2718 and averaged over the available years of data (which ranged from 1 to 3 years). Data on retained earnings and market value were taken from 1990 data, where available.

[16] See Section Two for a description of the MACT standards cost categories.

6.2.2 Postcompliance Analysis

EPA undertakes postcompliance analysis for those firms found to be financially viable in the baseline analysis (i.e., those firms for which the baseline results are "bankruptcy unlikely" or "indeterminate").[17] The total number of potentially affected firms in the postcompliance analysis is adjusted downward to exclude the baseline bankruptcies. In this way incremental bankruptcies associated with the Final Pharmaceutical Industry Effluent Guidelines can be identified under all three baseline scenarios.

Postcompliance bankruptcy predictions are based on changes in the financial status of a firm as a result of incremental pollution control costs.[18] The change in a firm's bankruptcy potential as a result of incremental pollution control costs, as predicted by the Altman Z-score or Z′-score, is determined using firm-specific capital and annual O&M costs associated with each regulatory option. These options are analyzed separately (costs for each option are applied to firms one at a time) and then as a group under a "selected options scenario." Since firms can own facilities in more than one subcategory, the combined effect of all selected options must be determined. As noted in Section Four the selected options are BAT-A/C (with revised BPT) for A/C directs, No Action (but with revised BPT) for B/D directs, and PSES-A/C and PSES-B/D for both A/C and B/D indirects. For the postcompliance analysis, the relevant survey data (total assets, total liabilities, and EBIT) are adjusted to reflect annual facility compliance costs for all facilities owned by a particular company.[19] Compliance costs for each facility owned by each company are incorporated into the analysis as follows:

- Postcompliance Total Assets = Total Assets + Capital Cost **(3)**
- Postcompliance Total Liabilities = Total Liabilities + Capital Cost **(4)**

[17] As noted above, EPA considers firms with Z-scores that fall in the "indeterminate" range to be viable operations, although the financial stability of these firms is somewhat uncertain.

[18] The annualized pollution control costs for each effluent guideline option were calculated with the cost annualization model described in Section Four.

[19] To estimate firm-level impacts at multifacility firms owning pharmaceutical facilities with a survey weight of 2, EPA assigned costs for both the surveyed and nonsurveyed facility to the firm.

- Postcompliance EBIT = EBIT – (Postcompliance Change in EBIT)[20, 21] **(5)**

The postcompliance analysis is performed under the assumption that the industry cannot pass through any portion of compliance costs to its customers.

Note that even if a firm is considered likely to fail, its facilities (as determined in the facility closure analysis) might not close. In the cases where a firm is considered likely to fail, its viable facilities could be sold as part of the company liquidation process and operated successfully under different ownership. Also note that some facilities could be sold (and continue to operate) to raise the necessary capital to finance the installation of pollution control equipment at a firm's remaining facilities. Thus multifacility firms that are projected to fail postcompliance but that do not have facilities that are estimated to close (as discussed in Section Five) are not considered as severely affected as firms that are estimated to fail and also must close some or all of their facilities. Single-facility firms that fail are assumed to be sold, so the primary impact to these firms is their loss of independent status, with one exception. If a single-facility firm both fails *and* has zero or negative earnings postcompliance, EPA assumes this firm might be liquidated. EPA individually investigates all postcompliance failures to determine if they are single-facility firms with zero or negative net income. A failure without closure is considered to be a lesser impact than closure and, further, is likely to

[20] These calculations assume 100 percent financing of compliance equipment through long-term debt, although tax shield on interest payments is not included (see Appendix A). Firms are assumed to incur all compliance costs for all facilities regardless of whether the facilities close in the baseline or postcompliance facility-level analyses, since liquidation and other costs associated with a facility closure will not exceed the compliance costs associated with a closing facility. Note that working capital and owner equity do not change with compliance costs because current assets and liabilities are assumed to be unaffected by long-term debt and total assets and total liabilities are assumed to change in tandem (i.e., as debt is paid off, depreciation reduces the book value of the asset).

[21] The postcompliance change in EBIT (in absolute value terms) is calculated using the cost annualization model described in Section Four. The total pretax cash outflows calculated by this model are composed of cash outflows for depreciation and O&M. The change in EBIT related to compliance costs corresponds to the change in O&M plus the change in the depreciation expenses. EPA adds the present value (PV) of depreciation to the PV of O&M payments to calculate the PV of the change in EBIT. This value is then annualized, because the Altman Z analysis is a period-by-period analysis (i.e., a firm's health is analyzed on the basis of one or more "snapshots" corresponding to, for example, quarterly or annual accounting reports).

have only a small impact on employment in the industry.[22] EPA also individually investigates any postcompliance failures to determine if multifacility firms own facilities that do not appear self-supporting in the various baselines. Of all the baseline closures identified in Section Five, only those facilities belonging to firms that do not appear financially able to support these facilities are considered true baseline closures.

6.3 BASELINE AND POSTCOMPLIANCE ALTMAN Z-SCORE RESULTS

6.3.1 Baseline Altman Z-Score Results

Table 6-1 presents the baseline results of the Altman Z-score analysis, grouped according to baseline and subcategory. The table presents the total number of firms in each of the Z-score categories (i.e., "bankruptcy likely," "indeterminate," and "bankruptcy unlikely"). As stated previously, an Altman Z-score below 1.81 (public) or 1.23 (private) indicates that bankruptcy is likely; a score above 2.67 (public) or 2.90 (private) indicates that bankruptcy is unlikely. Z-scores between these two groups are indeterminate.

The results in Table 6-1 indicate that under Baseline 1 (no MACT standards costs considered) 18 firms are likely to fail before the effects of any regulatory costs are considered. These 18 firms are 9.6 percent of the total number of firms in the analysis. Most of these firms (13) own B/D indirect facilities. One additional firm fails under the assumptions of Baseline 2 and two additional firms fail under the assumptions of Baseline 3 (compared with Baseline 1).

6.3.2 Postcompliance Altman Z-Score Results — "Bankruptcy Likely"

Table 6-2 presents the results of the postcompliance Altman Z analysis under all three baselines. In Baseline 1, firms potentially facing bankruptcy (or loss of independent status) under the selected options total four firms, or 2.4 percent of all firms. One of these same firms fails under the initial Baseline 2 assumptions,

[22] Employment losses associated with firms that fail but whose facilities do not close are assumed to lose 10 percent of their workers due to acquisition and consolidation of the firms' viable facilities. (See Section Seven)

Table 6-1

Baseline Firm Failures By Subcategory

Subcategory	Total Number of Firms *	Baseline 1		Total Number of Firms	Baseline 2		Total Number of Firms	Baseline 3	
		Number **	% of Total		Number	% of Total		Number	% of Total
Direct Discharge									
A/C	19	1	0.5%	19	1	0.5%	19	1	0.5%
B/D	11	2	1.1%	11	2	1.1%	11	2	1.1%
Indirect Discharge									
A/C	69	6	3.2%	69	7	3.7%	69	8	4.3%
B/D	95	11	5.9%	95	11	5.9%	95	11	5.9%
All Firms									
Selected Options	187	18	9.6%	187	19	10.2%	187	20	10.7%

* Three firms were not included due to insufficient data.

** The total number of firms column adds up to more than the actual number of firms because some firms own more than one type of facility. The total includes 7 firms with non-discharging facilities.

Source: Section 308 Survey Data, SEC Data, and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

Table 6-2

Postcompliance Firm Failures By Option

Options	Total Number of Firms *	Baseline 1		Total Number of Firms	Baseline 2		Total Number of Firms	Baseline 3	
		Number **	% of Total		Number	% of Total		Number	% of Total
Direct Discharge									
BAT-A/C (with BPT)	18	0	0.0%	18	0	0.0%	18	0	0.0%
BAT-B/D (with BPT)	9	0	0.0%	9	0	0.0%	9	0	0.0%
Indirect Discharge									
PSES-A/C	63	3	1.8%	62	2	1.2%	61	1	0.6%
PSES-B/D	84	1	0.6%	84	1	0.6%	84	1	0.6%
All Firms									
Selected Options	169	4	2.4%	168	3	1.8%	167	2	1.2%

* Three firms were not included due to insufficient data.

** The total number of firms column adds up to more than the actual number of firms because some firms own more than one type of facility. The total includes 7 firms with non-discharging facilities.

Source: Section 308 Survey Data, SEC Data, and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

so does not appear as a postcompliance failure under Baseline 2. Two of these firms fail under the initial Baseline 3 assumptions, so they also do not appear as postcompliance failures under Baseline 3. To be conservative, EPA assumes the four firm failures are attributable to the Final Pharmaceutical Industry Effluent Guidelines, regardless of baseline.

Three of these firms are A/C indirects and one is a B/D indirect. One of the A/C indirects and the B/D indirect are single-facility firms. The single-facility A/C indirect has negative firm-level earnings (EBIT) postcompliance (but not in any of the baselines). Thus EPA considers this firm likely to fail and close. The B/D indirect firm has positive earnings (EBIT) postcompliance. Although it is likely to lose its financial independence, EPA believes it will be a viable facility and will remain open postcompliance. One of the A/C indirect facilities is owned by a multifacility firm, but it is the only facility owned by this firm that is covered by the Final Pharmaceutical Industry Effluent Guidelines. EPA determined that the facility would not close postcompliance in the facility-level analysis in Section Five. Thus the Agency believes this facility is likely to be sold but will continue to operate postcompliance. The firm is thus considered most likely to lose ownership of this facility, but it is counted as a failure to be conservative. The fourth firm owns two A/C indirect facilities, both of which have positive net facility-level earnings (posttax operating earnings) postcompliance. EPA considers these facilities likely to be sold as viable continuing operations but, again, to be conservative, the firm itself is considered a failure postcompliance as a result of the Final Pharmaceutical Industry Effluent Guidelines. Thus out of the four firm failures projected to occur, only one is expected to result in both a firm failure and a facility closure. The other three firms will incur substantial impacts up to and including firm failure (although in reality they might not fail, but instead might be forced to sell their facilities).

This analysis further shows that all facilities projected to close in the baseline facility closure analysis can be supported by their firms postcompliance without significant impact on these firms.

6.3.3 Postcompliance Altman Z-Score Results — Change From Healthy to Indeterminate Status

Table 6-3 presents the results of an analysis looking at the numbers of facilities that change from Altman Z-scores of greater than 2.67 or 2.90 (bankruptcy unlikely) to less than 2.67 or 2.90 but greater than 1.81 or 1.23 (status "indeterminate") for the selected options scenario. As the table shows, four firms change financial status in this manner across all three baselines as a result of the Final Pharmaceutical Industry Effluent Guidelines. This result is considered a lesser impact than bankruptcy, because these firms might not be on track to failure and probably have more time and flexibility to improve their financial condition than those firms whose scores fall in the "bankruptcy likely" category.

Table 6-3

Indeterminate Analysis
(among firms that are considered "healthy" in the Baseline)

Options	Total Number of Firms *	Baseline 1 Closures		Baseline 2 Closures		Baseline 3 Closures	
		Number	% of Total	Number	% of Total	Number	% of Total
Direct Discharge							
BAT-A/C (with BPT)	19	0	0.0%	0	0.0%	0	0.0%
BAT-B/D (with BPT)	11	0	0.0%	0	0.0%	0	0.0%
Indirect Discharge							
PSES-A/C	69	3	4.3%	3	4.3%	3	4.3%
PSES-B/D	95	1	1.1%	1	1.1%	1	1.1%
All Firms							
Selected Options	187	4	2.1%	4	2.1%	4	2.1%

* The total number of firms column adds up to more than the actual number of firms because some firms own more than one type of facility. The total includes 7 firms with non-discharging facilities

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

SECTION SEVEN

NATIONAL AND REGIONAL EMPLOYMENT IMPACTS AND TOTAL OUTPUT LOSSES

This section of the EA assesses the regional and national employment impacts of the Final Pharmaceutical Industry Effluent Guidelines, both separately and together with the impacts from the MACT standards rule. It also discusses output losses to the national economy induced by revenue losses in the pharmaceutical industry. Only BAT, BPT, and PSES options are discussed here;[1] Section Five discusses impacts from NSPS and PSNS options.

EPA examines national-level employment losses and gains that will occur throughout the economy in response to the reallocation of expenditures caused by implementation of the Final Pharmaceutical Industry Effluent Guidelines, both separately and together with the impacts of the MACT standards rule. EPA also examines the losses of employment in the national-level economy that result from employment losses due to postcompliance facility closures and firm failures in the pharmaceutical industry. Additionally, since employment losses from closures and failures could overstate or understate employment losses based on reductions in output, EPA estimates direct losses to the pharmaceutical industry based on output losses (assuming no costs can be passed on to consumers). These losses are tempered by gains within that industry (due to direct hiring of pollution control equipment operators within the industry), so in this analysis EPA also calculates a net direct loss (or gain) of employment. Finally, EPA examines regional-level losses to determine impacts on communities.

Pollution control expenditures divert investment away from production by pharmaceutical establishments, which leads to direct employment losses and to a reduction in pharmaceutical production. These losses are offset by gains in employment and production in the firms that manufacture the pollution control equipment and by gains in employment related to installing and operating the equipment. A portion of these gains will most likely occur in the pharmaceutical industry itself (labor to operate pollution control equipment). These gains and losses can be measured using input-output (I-O) analysis.

[1] There are no costs associated with Best Conventional Pollutant Control Technology (BCT).

To compute either regional- or national-level employment changes, output effects or direct employment losses such as facility closures must be considered. Output loss, as defined for the purposes of I-O analysis, is measured as the total production loss multiplied by the unit price of that production, or the gross revenue loss to the industry. Pharmaceutical industry investments in compliance equipment and the costs of operating the equipment translate directly into output losses in the pharmaceutical industry (assuming none of these costs is passed through to customers); that is, the costs of compliance equal the output losses, which is consistent with economic theory under a zero cost passthrough scenario (with a perfectly elastic demand curve, the supply curve shifts down by the total incremental unit cost of compliance leading to reduced production and revenues). Declines in production at pharmaceutical establishments affect the revenues of input industries (industries that supply goods and services to the pharmaceutical industry), which further results in employment declines. These shifts, in turn, eventually result in a reduction of household consumption by workers in both the pharmaceutical industry and input industries, decreasing demand for consumer products at the national level.

Firsthand impacts, in this case those on the pharmaceutical industry, are known as direct effects, impacts that continue to resonate through the economy are known as indirect effects (effects on input industries), and effects on consumer demand are known as induced effects. Such effects are tracked both nationally and regionally in massive I-O tables prepared by the U.S. Department of Commerce's Bureau of Economic Analysis (BEA). For every dollar spent in a "spending industry" (or for every employment change in the directly affected industry), these tables identify the portion spent (or every employment change) in contributing or vendor industries and the portion spent by consumers (or employment change as a result of a change in consumption).[2]

For example, as a result of the Final Pharmaceutical Industry Effluent Guidelines, a pharmaceutical facility might purchase equipment to meet the effluent guidelines equivalent to BAT-A/C. One piece of this equipment could be a tank to hold wastewater. To make the tank, the manufacturer would purchase stainless steel. The steel manufacturer would purchase iron ore, coke, energy sources, and other commodities. Thus a portion of a dollar spent by the pharmaceutical industry becomes a smaller portion of a dollar spent by the tank manufacturer, and a smaller portion of a dollar spent by the steel manufacturer, and so on. These

[2] Direct employment effects such as employment losses from postcompliance facility closures or firm failures also can be used to derive national- and regional-level impacts using direct-effect multipliers.

iterations are captured in BEA's I-O tables and summarized as regional and national multipliers for output (revenues). BEA also has determined average wages and the proportion of output in each industry that goes to employee earnings and, as a result, the number of employees or full-time equivalents (FTEs)[3] associated with each $1 million change in output. I-O analysis provides a straightforward framework as long as the direct effects to the industry are small and certain limiting assumptions about technology are valid (e.g., constant returns to scale and fixed input ratios).

As noted above, I-O analysis uses the multipliers derived by BEA to determine both output and employment effects. There are national-level multipliers and regional-level multipliers. National-level multipliers used here include final-demand output multipliers (which are used to estimate total U.S. economy effects when output changes in a specific industry), final-demand employment multipliers (which are used to estimate the change in total U.S. employment when output changes in a specific industry), and direct-effect employment multipliers (which are used to estimate the change in U.S. employment given a change in employment in a specific industry). The regional multipliers used here are direct-effect employment multipliers (which are used to estimate a state-wide change in employment given a change in employment in a specific industry in a specific state). All of these multipliers will be discussed in more detail below.

The analysis of employment and output losses (as well as related impacts) is divided into two parts. Section 7.1 analyzes the national-level impacts of the Final Pharmaceutical Industry Effluent Guidelines on both labor and output using both direct output effects and direct employment effects. It also discusses the net, direct impacts on the pharmaceutical industry based on reductions in production resulting from compliance costs and the impacts of output and employment from the combined Pharmaceutical Industry Effluent Guidelines and MACT standards rule. Section 7.2 examines the regional impacts associated with employment losses resulting from facility closures and/or firm failures.

[3] One FTE = 2,080 labor hours = 1 person-year of employment.

7.1 NATIONAL-LEVEL OUTPUT AND EMPLOYMENT IMPACTS

7.1.1 Introduction

To comply with the Final Pharmaceutical Industry Effluent Guidelines, facilities might need to install and operate pollution control systems. The costs for these systems reduce output and employment in the pharmaceutical industry and increase output and employment in the sectors that manufacture, install, and operate pollution control equipment.

Despite the fact that employment losses and gains associated with pollution control expenditures tend to act as counterbalances, there are differences in the national-level economy under baseline and postcompliance scenarios. Because industries vary in the effect they have on the national-level economy and their labor intensity, output and employment losses may or may not exceed output and employment gains, leading to either small net losses or small net gains.

7.1.2 Methodology for Estimating National-Level Output and Employment Impacts

EPA estimates two categories of national-level impacts associated with the Final Pharmaceutical Industry Effluent Guidelines: impacts on output in the economy as a whole (in dollars) and impacts on national employment (in FTEs). Also discussed in this section is the method for determining direct employment losses occurring in the pharmaceutical industry alone, based on changes in output in the industry. These losses are compared to the employment losses attributable to facility closures or firm failures, which can be either smaller or larger than output-induced losses. Finally, this section discusses the method used to estimate output and employment gains and losses associated with the MACT standards rule and the combined rules.

7.1.2.1 National-Level Output Losses and Gains

The loss in national-level output associated with output loss in the pharmaceutical industry is estimated using the pretax capital and O&M costs of compliance. The pretax costs are used because I-O multipliers are based on changes in revenues, which are pretax numbers.

BEA industry 29.0100, which corresponds to SIC 283 (drugs), is the detailed industry category that most closely matches the portion of the pharmaceutical industry affected by the Final Pharmaceutical Industry Effluent Guidelines. The national-level output multiplier estimated by BEA for this industry grouping is 2.3882.[4] This multiplier represents the total dollar change in national output for all industries for each dollar change in the output of the pharmaceutical industry. Using the BEA multiplier and the output loss to the industry (equivalent to the pretax compliance costs to the industry, as discussed above), EPA estimates losses throughout the national economy in the following way:

Pretax Compliance Cost for Option x 2.3882 = National-Level Output Loss for Option

EPA also estimates the output gains in the economy using the following output multipliers[5] for the pollution control industries:

- For capital material costs:

  BAT and BPT: BEA Industry 42.0800 (pipes, valves, and pipe fittings); BEA Industry 49.0100 (pumps and compressors); BEA Industry 49.0700 (general industrial machinery and equipment); BEA Industry 36.1100 (concrete products, except block and brick); and BEA Industry 40.0600 (fabricated plate work),[6] with a weighted output multiplier of

[4] U.S. Department of Commerce, 1992. Table A-2.4—Total Multipliers, by Industry Aggregation, for Output, Earnings, and Employment. *Regional Input-Output Modeling System (RIMS II)*. Washington, DC: BEA, Regional Analysis Division, (RIMS II National Multipliers).

[5] *Ibid.*

[6] Includes tanks.

2.9487.[7] Capital material costs are assumed to be 90 percent of the total capital costs estimated for each option.

PSES: BEA Industry 42.0800 (pipes, valves, and pipe fittings); BEA Industry 49.0100 (pumps and compressors); BEA Industry 49.0700 (general industrial machinery and equipment); BEA Industry 40.0600 (fabricated plate work);[8] BEA Industry 40.0300 (heating equipment, except electrical and warm air furnaces); and BEA Industry 40.0400 (fabricated structural metal), with a weighted output multiplier of 2.9724.[9] Capital material costs are assumed to be 90 percent of the total capital costs estimated for each option.

- For installation costs (BAT, BPT, and PSES): BEA Industry 11.0000 (construction — new and maintenance and repair), with a multiplier of 3.1957. Installation costs are assumed to be 10 percent of total capital costs.

- For operating costs (BAT, BPT, and PSES): (1) Labor: BEA Industry 29.0100 (drugs), with a multiplier of 2.3882 (assumes that operators for pollution control equipment will be hired by the affected industry); (2) Materials: BEA Industry 27.0406 (chemical and chemical preparations, not elsewhere classified) with a multiplier of 2.9083; (3) Energy: BEA Industry 68.0100 (electric services [utilities]), with a multiplier of 2.2370. Labor, materials, and energy shares vary among options as discussed below.

Gains are calculated using the costs assigned to a cost component (e.g., materials cost x 2.9083 = national-level output gain associated with the materials portion of O&M cost). Labor, materials, and energy

[7] The weighted multiplier for BAT/BPT is developed assuming that 20 percent of capital costs is piping, 10 percent is pumps, 10 percent is general industrial machinery (filter press), 35 percent is concrete, and 25 percent is tanks. These breakdowns, as well as those discussed in the bullets later in this section, are estimated on the basis of assumptions developed by EPA's technical contractor (Tim Brenza, Eastern Research Group, Inc., Industry Categories for Multipliers. Memorandum to Record, January 29, 1998). These same assumptions are applied to the development of the employment multiplier breakdown discussed later.

[8] Includes tanks.

[9] The weighted multiplier for PSES is developed assuming that 50 percent of capital costs is piping, 4 percent is pumps, 1 percent is general industrial machinery, 20 percent is tanks, 10 percent is heating equipment, and 15 percent is fabricated structural metal. These breakdowns, as well as those discussed in the following bullets, are estimated on the basis of assumptions developed by EPA's technical contractor (Tim Brenza, Eastern Research Group, Inc., Industry Categories for Multipliers. Memorandum to Record, January 29, 1998). These same assumptions are applied to the development of the employment multiplier breakdown discussed later.

shares for all options have been estimated separately in cost models and vary according to option.[10] EPA calculates output gains for the remaining options similarly using their respective labor, materials, and energy costs. When all the gains associated with pollution control industries are aggregated, EPA can estimate the total output gains attributable to the Final Pharmaceutical Industry Effluent Guidelines. To determine a net loss or gain, EPA then compares the losses and gains in the economy.

7.1.2.2 National-Level Employment Losses and Gains

In calculating national-level employment impacts, the Agency first uses a similar approach to that used to calculate output effects. Based on pharmaceutical industry output, BEA (RIMS II National Multipliers) has estimated a final-demand multiplier for national-level employment of 19.5. This number represents the total change in the number of jobs in all industries nationally for each $1 million change in output delivered to final demand by the pharmaceutical industry.[11] Therefore, to calculate employment impacts, EPA divides the output loss of the pharmaceutical industry, measured as the annual pretax compliance cost, by $1 million and multiplies this figure by BEA's employment multiplier.[12]

Another estimate of impact on employment can be achieved by using total postcompliance closures/failures and the associated employment losses, multiplied by the national-level, direct-effect employment multiplier of 5.0798. These two types of losses (output and closure-related losses) overlap (that is, the larger of the two losses includes the smaller of the two losses), but they correspond to different driving factors. Closures/failures are driven by individual facility or firm financial situations, but are not directly related to market conditions, whereas output-related losses do reflect market conditions but would not reflect conditions at individual firms or facilities.

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[10] Cost breakdowns for labor, materials and energy were developed by EPA's technical contractor; Tim Brenza, Eastern Research Group, Inc. Cost Breakdowns for Labor, Materials and Energy. Memorandum to Record, May 29, 1998.

[11] Employment impacts calculated using a final-demand multiplier include direct, indirect, and induced effects.

[12] Losses are inflated to 1992 dollars because BEA's national multipliers are based on 1992 data. EPA uses *Engineering News Record*, 1997. "Construction Cost Index," March 31, for inflating.

Output-based losses can be thought of as longer-term losses associated with longer-term market equilibrium, whereas losses associated with closures and failures can be considered the more immediate impact of the rule before market equilibrium is achieved. Thus output-based losses may be greater than or less than the losses estimated on the basis of closures and failures, which means that nonclosing facilities might gain or lose production and employment depending on how many facilities close. If no facilities close, nonclosing facilities might lose some production and employment. If many facilities close, nonclosing facilities might actually gain production and employment if closure losses "overshoot" the expected losses at market equilibrium. Note, however, that both the output-based employment effects and the closure/failure employment effects derived here are worst-case impacts within the pharmaceutical industry since EPA assumes the industry cannot pass through the costs of compliance to consumers.

Employment gains are estimated using the final-demand multipliers for each of the pollution control industries listed above. These multipliers are:

- For capital material costs:

  BAT and BPT: BEA Industry 42.0800 (pipes, valves, and pipe fittings); BEA Industry 49.0100 (pumps and compressors); BEA Industry 49.0700 (general industrial machinery and equipment); BEA Industry 36.1100 (concrete products, except block and brick); and BEA Industry 40.0600 (fabricated plate work),[13] with a weighted employment multiplier of 31.35.[14]

  PSES: BEA Industry 42.0800 (pipes, valves, and pipe fittings); BEA Industry 49.0100 (pumps and compressors); BEA Industry 49.0700 (general industrial machinery and equipment); BEA Industry 40.0600 (fabricated plate work);[15] BEA Industry 40.0300 (heating equipment, except electrical and warm air furnaces); and BEA Industry 40.0400 (fabricated structural metal), with a weighted employment multiplier of 30.32.[16]

- For installation costs (BAT, BPT, and PSES): BEA Industry 11.0000 (construction — new and maintenance and repair), with a multiplier of 21.5.

[13] Includes tanks.

[14] Weighting is the same as that used for the output gains analysis.

[15] Includes tanks.

[16] Weighting is the same as that used for the output gains analysis.

- For operating costs (BAT, BPT, and PSES): (1) Labor: BEA Industry 29.0100 (drugs), with a multiplier of 19.5 (assumes that operators for pollution control equipment will be hired by the affected industry); (2) Materials: BEA Industry 27.0406 (chemicals and chemical preparations, not elsewhere classified) with a multiplier of 23.7; and (3) Energy: BEA Industry 68.0100 (electric services [utilities]), with a multiplier of 15.8.

EPA computes employment gains by multiplying the appropriate industry shares of the pollution control costs times the appropriate multiplier. After aggregating all gains, EPA compares national-level losses and gains to compute the net employment change resulting from the Final Pharmaceutical Industry Effluent Guidelines. This net change can then be compared to national-level employment to gauge the magnitude of employment impacts on the national economy.

7.1.2.3 Total Direct Employment Losses in the Pharmaceutical Industry

As noted above, the employment losses from closures/failures might understate direct employment losses in the pharmaceutical industry. Therefore, EPA also must determine whether employment losses from nonclosing facilities occur, or whether some employment (and production) gains accrue to nonclosing facilities. EPA thus conducts another employment loss analysis that allows net losses to be computed. This analysis is based on output effects assuming no cost passthrough to consumers and gains in labor associated with operating pollution control equipment. The analysis uses total output losses associated with the selected options scenario to reflect the reduction in output that would affect employment in the pharmaceutical industry alone. EPA then computes the direct employment losses in the pharmaceutical industry alone. As with the national-level analysis described above, employment losses in the industry might be offset by employment gains, because it is likely pharmaceutical facilities will hire or transfer workers from productive operations to operate the pollution control equipment installed.

This output loss, which was converted to total employment losses using the BEA multiplier of 19.5 FTEs per $1 million change in the output for the pharmaceutical industry, includes all direct, indirect, and induced employment effects specifically related to changes in output in the pharmaceutical industry alone. To estimate direct losses only (losses only in the pharmaceutical industry), EPA multiplies total net employment losses by the inverse of the national-level direct-effect employment multiplier (5.0798). The direct-effect multiplier represents the change in total (direct, indirect, and induced) employment for each unit change in direct employment; its inverse, therefore, represents the direct employment change portion of total

employment impacts. Direct losses can be compared to total industry baseline employment to gauge the magnitude of employment impacts within the industry. They also can be compared to losses associated with facility closures/firm failures to determine how many employees, if any, are lost at nonclosing facilities after accounting for potential gains.

Employment losses associated with failures/closures are estimated using the Section 308 Survey data on facility-level employment. For every closure or closure/failure, EPA assumes the entire employment at a facility is lost. For firm failures where the facility or facilities are considered financially viable, EPA assumes 10 percent of total firm employment is lost (i.e., the facilities are sold, but some administrative employment is lost due to acquisition and/or merger).

The direct employment losses, however, are only a fraction of the employment losses that might affect the national economy; as discussed earlier, there are indirect and induced losses of employment also to consider. These indirect and induced losses can be estimated using the national-level BEA direct-effect multipliers. The national-level direct-effect multiplier for the pharmaceutical industry is 5.0798. The calculation for determining the total, national-level employment loss based on closures/failures is:

Direct Employment Loss x Direct Effect Multipliers = Total Direct, Indirect, and Induced Losses.

7.1.2.4 Output and Employment Effects Associated with the Combined Rules

Using the same methodology as described above, and assuming that the breakdowns and multipliers are identical to those used for PSES-A/C (the technologies likely to be used for achieving PSES-A/C and the MACT standards rule are very similar) and the costs associated with the MACT standards rule, EPA calculates the output and employment losses and gains associated with MACT standard costs for wastewater emission controls and total MACT standard costs for the facilities in the Final Pharmaceutical Industry Effluent Guidelines analysis. These impacts are then summed with impacts from the Final Pharmaceutical Industry Effluent Guidelines to estimate the impacts from both rules combined.

7.1.3 National-Level Output and Employment Impacts

7.1.3.1 National-Level Output Losses From the Final Pharmaceutical Industry Effluent Guidelines

Table 7-1 shows the total gross, national-level, worst-case output losses associated with the Final Pharmaceutical Industry Effluent Guidelines. Using the output multiplier of 2.3882, national-level output losses are estimated to range from $0 to $86 million per year, depending on the option, with total losses under the selected options estimated to be $118 million.

Table 7-2 shows the total gross national-level output gains associated with purchasing, installing, and operating pollution control equipment. The national-level output gains for each option are estimated to range from $0 to $100 million per year, with a total output gain of $136 million for all selected options. The net annual gains in national-level output for each option are estimated to range from $0 million to $13 million per year, depending on the option, with total net gains estimated to be $18 million (see Table 7-3).

7.1.3.2 National-Level Employment Losses/Gains from the Final Pharmaceutical Industry Effluent Guidelines

Table 7-4 presents the national-level employment losses associated with the lost pharmaceutical industry output. EPA converts the industry output losses into millions of 1992 dollars[17] and multiplies these losses by the employment multipliers to determine total annual employment losses of 0 to 742 FTEs, depending on the option. The total output-based loss over the entire U.S. economy for all selected options is estimated to be 1,014 FTEs. The total number of employment losses associated with closures/failures is estimated to be 139 FTEs.[18] When indirect and induced losses are added to these direct losses, losses in the economy from closures/failures total 706 FTEs. The output-based loss includes these 706 FTEs.

[17] BEA's RIMS II National Multipliers are based on 1992 data and thus, all 1990 dollars must be inflated when compared to the total employment losses in the economy associated with closures/failures.

[18] These losses stem from one facility failure and closure (94 FTEs), three firm failures (combined 25 FTEs), and one facility closure (20 FTEs) which closes only under Baseline 3 when total MACT costs are included.

Table 7-1

Annual National-Level Output Losses (millions of 1990 dollars)

Selected Option	Total Estimated Ouput Loss in the Pharmaceutical Industry	Output Multiplier	National-Level Output Losses
BPT-A/C	$2.02	2.3882	$4.82
BPT-B/D	$1.12	2.3882	$2.68
BAT-A/C	$2.93	2.3882	$6.99
PSES-A/C	$36.13	2.3882	$86.29
PSES-B/D	$7.17	2.3882	$17.12
Total of Selected Options	$49.36		$117.89

Source: Output loss is pretax annualized cost of capital and O&M costs shown in Table 4-3 in Section 4. Output multiplier is from U.S. Department of Commerce, 1992. Table A-2.4--Total multipliers, by Industry Aggregation, for Output, Earnings and Employment. Regional Input-Output Modeling System (RIMS II). BEA, Regional Analysis Division.

Table 7-2

Annual National-Level Output Gains (millions of 1990 dollars)

Item	BPT-A/C	BPT-B/D	BAT-A/C	PSES-A/C	PSES-B/D	Total
Total Capital Cost (Annualized Over 16 Years at 7%)	$0.26	$0.19	$0.59	$8.56	$2.34	$11.93
Capital Materials Cost	$0.23	$0.17	$0.53	$7.70	$2.10	$10.74
Capital Materials Multiplier	2.9487	2.9487	2.9487	2.9724	2.9724	
Output Gain (Capital Materials)	$0.68	$0.50	$1.56	$22.90	$6.25	$31.90
Installation Cost	$0.03	$0.02	$0.06	$0.86	$0.23	$1.19
Installation Cost Multiplier	3.1957	3.1957	3.1957	3.1957	3.1957	
Output Gain (Installation)	$0.08	$0.06	$0.19	$2.74	$0.75	$3.81
Total O&M Cost	$1.76	$0.93	$2.34	$27.57	$4.83	$37.43
Labor Share	$1.04	$0.69	$0.97	$11.55	$0.88	$15.13
Labor Multiplier	2.3882	2.3882	2.3882	2.3882	2.3882	
Output Gain (Labor)	$2.49	$1.65	$2.31	$27.58	$2.10	$36.14
Materials Share	$0.60	$0.18	$1.15	$15.66	$3.92	$21.51
Materials Multiplier	2.9083	2.9083	2.9083	2.9083	2.9083	
Output Gain (Materials)	$1.74	$0.52	$3.35	$45.55	$11.39	$62.56
Energy Share	$0.12	$0.06	$0.21	$0.36	$0.04	$0.79
Energy Multiplier	2.2370	2.2370	2.2370	2.2370	2.2370	
Output Gain (Energy)	$0.27	$0.14	$0.48	$0.80	$0.08	$1.77
Total Output Gain	$5.26	$2.87	$7.90	$99.57	$20.56	$136.17

Source: Capital and O&M costs are from EPA's Development Document. Multipliers are derived as discussed in the text of this report and obtained from BEA table.

Table 7-3

Net Annual National-Level Output Losses Associated with the Final Pharmaceutical Industry Effluent Guidelines (millions of 1990 dollars)

Selected Option	Total Annual Loss	Total Annual Gain	Net GAIN in National-Level Output
BPT-A/C	$4.82	$5.26	$0.44
BPT-B/D	$2.68	$2.87	$0.20
BAT-A/C	$6.99	$7.90	$0.91
PSES-A/C	$86.29	$99.57	$13.28
PSES-B/D	$17.12	$20.56	$3.45
Total of Selected Options	**$117.89**	**$136.17**	**$18.28**

Source: Tables 7-1 and 7-2.

Table 7-4

National-Level Employment Losses (FTEs)

Selected Option	Total Annual Output Loss in the Pharmaceutical Industry ($ MM 1990)	Loss in 1992 Dollars ($ MM 1992)	Output Employment Multiplier	Total Output-Based FTE Loss	Employment Losses Based on Facility Closures/Firm Failures	Direct Effect Employment Multiplier	Total Closure/Failure-Based FTE Loss
BPT-A/C	$2.02	$2.12	19.5	41	0	5.0798	0
BPT-B/D	$1.12	$1.18	19.5	23	0	5.0798	0
BAT-A/C	$2.93	$3.08	19.5	60	0	5.0798	0
PSES-A/C	$36.13	$38.06	19.5	742	138	5.0798	701
PSES-B/D	$7.17	$7.55	19.5	147	1	5.0798	5
Total Selected Options	**$49.36**	**$52.00**		**1,014**	**139**		**706**

Source: Table 7-1; Employment multipliers are from U.S. Department of Commerce, 1992. Table A-2.4--Total Multipliers, by Industry Aggregation, for Output, Earnings and Employment. Regional Input-Output Modeling System (RIMS II). BEA, Regional Analysis Division.
1990 dollars are inflated to 1992 dollars using the Engineering News Record's Construction Cost Index (0.9568).

Table 7-5 presents the national-level employment gains associated with the output gains in the pollution control industries. These gains range from 0 to 900 FTEs, depending on option, with total gains estimated to be 1,232 FTEs.

As Table 7-6 shows, net employment gains range from 0 to 158 FTEs, depending on option. The total net gain in national-level employment based on output is 218 FTEs for all selected options. (A gain of 526 FTES would be computed if national-level losses are estimated solely on the basis of closures/failures.)

7.1.3.3 Direct Employment Losses in the Pharmaceutical Industry from the Effluent Guidelines

As noted above, the losses associated with postcompliance facility closures or firm failures could overstate or understate longer-term losses in the pharmaceutical industry. The actual output loss, calculated for the pharmaceutical industry using pretax annual costs of compliance, totals $52 million annually for all selected options (1992 dollars) or less than 1 percent of the $56.7 billion in pharmaceutical revenues in 1990.[19] This output loss would result in a nationwide employment loss of 1,014 FTEs associated with output losses occurring strictly in the pharmaceutical industry, based on the final-demand employment multiplier of 19.5 FTEs per $1 million output change (see Table 7-4 and Table 7-7).

These numbers, however, include the direct, indirect, and induced employment losses, (see beginning of Section Seven for definition) as well as losses that might be offset by gains within the pharmaceutical industry. Employment gains (direct, indirect, and induced) expected due to the need to operate the pollution control equipment, as shown in Table 7-5, are estimated to be 0 to 237 FTEs, for a total of 311 FTEs over the selected options. Assuming pharmaceutical firms will choose to transfer employees from productive operations or hire new employees to operate the pollution control equipment rather than contract for these services from other industries, 100 percent of these employment gains will be felt in the pharmaceutical industry itself (see Table 7-7). Thus the total net loss associated with pharmaceutical facilities (and still including direct, indirect, and induced losses) ranges from 0 to 505 FTEs, depending on option, and totals 703 FTEs over all selected options (i.e., 1,014 FTEs lost – 311 FTEs gained = 703 FTEs lost). Given this total net loss in employment, the inverse of the direct-effect multiplier (i.e., 1/multiplier) can be used to

[19] U.S. Bureau of the Census. 1997. *Statistical Abstract of the United States: 1997*. Washington, DC: U.S. Government Printing Office.

Table 7-5

National-Level Employment Gains (FTEs) (millions of 1992 dollars)

Item	BPT-A/C	BPT-B/D	BAT-A/C	PSES-A/C	PSES-B/D	Total
Total Capital Cost (Annualized Over 16 Years at 7%)	$0.27	$0.20	$0.62	$9.02	$2.46	$12.57
Capital Materials Cost	$0.24	$0.18	$0.56	$8.12	$2.21	$11.31
Capital Materials Employment Multiplier	31.35	31.35	31.35	30.32	30.32	
Employment Gain (Capital Materials)	8	6	18	246	67	344
Installation Cost	$0.03	$0.02	$0.06	$0.90	$0.25	$1.26
Installation Cost Employment Multiplier	21.5	21.5	21.5	21.5	21.5	
Employment Gain (Installation)	1	0	1	19	5	27
Total O&M Cost	$1.85	$0.98	$2.46	$29.05	$5.09	$39.43
Labor Share	$1.10	$0.73	$1.02	$12.17	$0.93	$15.94
Labor Employment Multiplier	19.5	19.5	19.5	19.5	19.5	
Employment Gain (Labor)	21	14	20	237	18	311
Materials Share	$0.63	$0.19	$1.22	$16.50	$4.13	$22.66
Materials Employment Multiplier	23.7	23.7	23.7	23.7	23.7	
Employment Gain (Materials)	15	4	29	391	98	537
Energy Share	$0.13	$0.06	$0.00	$0.38	$0.04	$0.83
Energy Employment Multiplier	15.8	15.8	15.8	15.8	15.8	
Employment Gain (Energy)	2	1	4	6	1	13
Total Employment Gain	47	26	71	900	189	1,232

Source: Capital and O&M costs are from EPA's Development Document. Multipliers are derived as discussed in the text of this report and obtained from BEA tables.

Table 7-6

Net Annual National-Level Employment Losses Associated with the Final Pharmaceutical Industry Effluent Guidelines (FTEs)

Selected Option	Total Annual Losses Based on Output	Total Annual Gain	Net GAIN in National-Level Employment Based on Output
BPT-A/C	41	47	5
BPT-B/D	23	26	3
BAT-A/C	60	71	11
PSES-A/C	742	900	158
PSES-B/D	147	189	42
Total of Selected Options	**1,014**	**1,232**	**218**

Source: Tables 7-4 and 7-5.

Table 7-7

Direct Employment Losses in the Pharmaceutical Industry (FTEs)

Selected Option	Total FTE Loss	Total FTE Gain	Net Total FTE LOSS	Net Direct FTE LOSS	Percent of Industry Employment
BPT-A/C	41	21	20	4	0.00%
BPT-B/D	23	14	9	2	0.00%
BAT-A/C	60	20	40	8	0.00%
PSES-A/C	742	237	505	99	0.05%
PSES-B/D	147	18	129	25	0.01%
Total of Selected Options	**1,014**	**311**	**703**	**138**	**0.08%**

Source: Tables 7-4 and 7-5. Industry employment from Section 308 survey.

calculate the direct employment losses. The direct-effect multiplier for the pharmaceutical industry is 5.0798, which means that for every direct job loss, there are an additional 4.0798 indirect and induced job losses.[20] Thus, the direct component of the net losses calculated is estimated to be 138 FTEs for all selected options, which is 0.08 percent of the estimated 184,000 FTEs (Section 308 Survey) employed in the affected portion of the pharmaceutical industry. This number is almost identical to the closure/failure-related losses estimated (139 FTEs), so any employment losses or gains occurring among nonclosing facilities will be negligible, assuming zero cost passthrough.

7.1.3.4 National-level Output and Employment Losses and Gains from Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule

Table 7-8 presents the output and employment gains expected from the MACT standards rule. Output gains associated with the MACT standards rule for wastewater emission controls and total MACT standards requirements (for facilities in the Final Pharmaceutical Industry Effluent Guidelines analysis) were estimated to be $24 and $112 million with employment gains of 227 and 1,017 FTEs, respectively. Table 7-9 presents the output and employment losses and net output and employment gains from the MACT standards rule and the combined rules. The net gain in national-level output associated with total MACT standards requirements is estimated to be $16 million and, when combined with the $18 million net gain associated with the selected effluent guideline options, the total net gain in national-level output for the combined rules becomes $34 million. The net gain in national-level employment associated with total MACT standards requirements is estimated to be 189 FTEs, yielding a net employment gain of 407 FTEs for the combined rules.

Table 7-10 presents direct output-related employment losses in the pharmaceutical industry for MACT standards rule. The annual postcompliance production loss associated with the total costs of the MACT standards rule for facilities in the Final Pharmaceutical Industry Effluent Guidelines analysis, as measured by annualized pretax costs of compliance, is estimated to be $42 million in 1992 dollars.[21] Multiplying this production loss by the final-demand employment multiplier of 19.5 yields a total loss of 828

[20] RIMS II National Multipliers.

[21] BEA's RIMS II National Multipliers are based on 1992 data and thus, all 1990 dollars must be inflated when compared to the total employment losses in the economy associated with closures/failures.

Table 7-8

Annual National-Level Output and Employment Gains for MACT standards

Item	Output Gains (millions of 1990 dollars)		Employment Gains (FTEs) (millions of 1992 dollars)	
	MACT standards for wastewater emission controls	Total MACT standards	MACT standards for wastewater emission controls	Total MACT standards
Total Capital Cost (Annualized Over 16 Years at 7%)	$3.27	$10.88	$3.45	$11.47
Capital Materials Cost	$2.94	$9.80	$3.10	$10.32
Capital Materials Multiplier	2.9724	2.9724	30.32	30.32
Output/Employment Gain (Capital Materials)	$8.75	$29.12	94	313
Installation Cost	$0.33	$1.09	$0.34	$1.15
Installation Cost Multiplier	3.1957	3.1957	21.5	21.5
Output/Employment Gain (Installation)	$1.05	$3.48	7	25
Total O&M Cost	$5.44	$29.44	$5.73	$31.01
Labor Share *	$2.18	$11.81	$2.30	$12.44
Labor Multiplier	2.3882	2.3882	19.5	19.5
Output/Employment Gain (Labor)	$5.21	$28.19	45	243
Materials Share *	$3.19	$17.25	$3.36	$18.17
Materials Multiplier	2.9083	2.9083	23.7	23.7
Output/Employment Gain (Materials)	$9.27	$50.17	80	431
Energy Share *	$0.07	$0.38	$0.07	$0.40
Energy Multiplier	2.2370	2.2370	15.8	15.8
Output/Employment Gain (Energy)	$0.16	$0.86	1	6
Total Output/Employment Gain	$24.44	$111.82	227	1,017

Source: Capital and O&M costs are from EPA's Development Document. Multipliers are derived as discussed in the text of this report and obtained from BEA table.

* Labor, materials, and energy shares of O&M are assumed to be equivalent to PSES-A/C percentages.

Table 7-9

Net Annual National-Level Output and Employment Losses Associated with Final Pharmaceutical Industry Effluent Guidelines and MACT standards

Rule	National-Level Output (millions of 1990 dollars)			National-Level Employment (FTEs)		
	Total Annual Loss	Total Annual Gain	Net GAIN in National-Level Output	Total Annual Loss	Total Annual Gain	Net GAIN in National-Level Employment
Total selected effluent guidelines options	$117.89	$136.17	$18.28	1,014	1,232	218
MACT standards for wastewater emission controls	$20.81	$24.44	$3.63	179	227	48
Total MACT standards	$96.30	$111.82	$15.52	828	1,017	189
Total combined rules	$214.19	$247.99	$33.80	1,842	2,249	407

Source: Table 7-8 and Table 4-4 (applying multipliers as in Tables 7-1 and 7-4) for MACT standards rule and Table 7-2 and 7-5 for the Final Pharmaceutical Industry Effluent Guidelines.

Table 7-10

Direct Employment Losses in the Pharmacaeutical Industry for MACT standards (FTEs)*

Rule	Annual Postcompliance Production Loss ($ MM 1990)	Output Loss in 1992 Dollars ($ MM 1992)	Final-Demand Employment Multiplier	Total FTE Loss	Total FTE Gain	Net Total FTE LOSS	Net Direct FTE LOSS	Percent of Industry Employment
Total selected effluent guidelines options	$49.36	$52.00	19.5	1,014	311	703	138	0.08%
MACT standards for wastewater emission control	$8.71	$9.18	19.5	179	45	134	26	0.01%
Total MACT standards	$40.33	$42.48	19.5	828	243	586	115	0.06%
Total combined rules	$89.69	$94.48	19.5	1,842	553	1,289	254	0.14%

Source: Table 7-9 for MACT standards rule and Table 7-1 and 7-7 for Final Pharmaceutical Industry Effluent Guidelines.

* Refer to text for explanation of MACT standards costs.

FTEs. Assuming that 40 percent of the MACT standards O&M cost goes to labor (which is the same assumption used for PSES-A/C, because the MACT standards rule is associated with the same technology on which PSES-A/C is based) and assuming 100 percent of these labor gains occur in the pharmaceutical industry (because workers are assumed to be transferred from productive operations to operate pollution control equipment), then the total employment gain associated with the labor to operate pollution control equipment resulting from the MACT standards rule is 243 FTEs (see Table 7-8). Comparing total gains and losses yields a total net loss of 586 FTEs for the MACT standards rule, which includes all direct, indirect, and induced losses. Multiplying this loss by the inverse of the direct-effect multiplier (i.e., 1/multiplier) yields a net direct employment loss of 115 FTEs, which is only 0.06% of total industry employment. Thus, direct net employment losses for both rules combined totals 254 FTEs, (138 from the Final Pharmaceutical Industry Effluent Guidelines and 115 from MACT standards rule, with rounding, or 0.14% of total industry employment. Closing firms/facilities are associated with employment losses totaling 139 FTEs. Thus nonclosing facilities might experience very small employment impacts (about 0.4 FTE per facility per year on average) from the combined rules, assuming zero cost passthrough.

7.2 REGIONAL EMPLOYMENT IMPACTS

7.2.1 Regional Analysis Methodology

The employment losses of concern in the regional-level analysis consist of two components: (1) employee layoffs associated with the facility closures and (2) employee layoffs associated with firm failures. (The output-based losses among nonclosing facilities calculated to occur are very small and will not have any effect on any one community). As discussed above, Section 308 Survey data on annual employment hours is used to calculate direct employment losses associated with facility closures/failures resulting from the Final Pharmaceutical Industry Effluent Guidelines on an FTE basis.

These losses are the direct employment losses associated with the Final Pharmaceutical Industry Effluent Guidelines that might have a significant impact on a region's economy. As in the case at the national level, direct losses can lead to indirect and induced losses at the regional level, which can be estimated using BEA regional direct-effect multipliers for the affected states in which closing/failing facilities or firms are

located. Note, however, that because these multipliers are derived for an entire state, they will most likely overstate the impacts within a smaller region (e.g., county or metropolitan statistical area [MSA]).

The direct-effect multiplier shows the number of total jobs lost in all industries given one job lost in the subject industry. For example, BEA tables show that one job lost in the pharmaceutical industry in the state of California will result in a total of 5.8464 jobs lost in all industries throughout the state. Thus the calculation is:

Direct Employment Loss x Direct-Effect Multiplier = Total Direct, Indirect, and Induced Losses

The significance to the community of employment losses is measured by their impact on the community's overall level of employment. Data necessary to determine the community impact include the community's total labor force and employment rate. The community employment information used in this analysis is from the Census Bureau's web page,[22] as estimated by the Bureau of Labor Statistics. For the purposes of this analysis, the community is defined as the MSA (if urban) or county (if rural) in which the facility is located and is assumed to represent the labor market area within which residents could reasonably commute to work. EPA evaluates the percentage increase in the unemployment rate (measured as 1 percent, for example, if the unemployment rate changes from 5 percent to 6 percent), to determine the severity of impact. The change in the unemployment rate is computed as:

Current Unemployment Rate-[(Current Unemployment + Postcompliance Employment Losses)/Labor Force]

Because the closures/failures are occurring among firms and facilities not affected by statistical weighting, the employment losses represented by these closures/failures will most likely occur only in the communities in which the affected facilities are located.

7.2.2 Results of the Regional Analysis

The largest employment loss associated with any one facility closure/failure occurs in a large urban area. The direct employment loss is 94 FTEs, and when indirect and induced effects are taken into account

[22] Http://www.census.gov/datamap/www/index.html.

for that state, the total loss becomes 395 FTEs. The county in which this facility is located has a labor force of approximately 400,000 with an unemployment rate of about 8 percent (1994 data, the most recent available).[23] The facility closure/failure would cause the unemployment rate to increase by only 0.1 percent. EPA concludes that the impact this facility closure/failure would have on this region's economy is negligible.

The most significant percentage change in regional employment patterns resulting from a facility closure occurs in a rural area with a very small county labor force. This closure leads to a direct employment loss of 20 FTEs, and when accounting for indirect and induced losses in that state, the total employment loss is 66 FTEs.[24] Although this region experiences the most significant employment impact from a closing/failing facility, the increase in the county unemployment rate due to this closure/failure is still less than 0.4 percent, which EPA considers minimal. Given these findings and given that all other firm failures result in changes in the unemployment rate of substantially less than 0.4 percent, none of the selected options (either with or without MACT standards costs) would have a noticeable economic impact on the affected communities.

[23] Http://www.census.gov. *Op. cit.*

[24] These employment losses occur only under Baseline 3 when total MACT standards costs are included.

SECTION EIGHT

OTHER SECONDARY IMPACTS

This section presents the results of several analyses, including analyses investigating the impacts of the Final Pharmaceutical Industry Effluent Guidelines (separately and together with the impacts of the MACT standards rule) on trade and the balance of payments, on decisions of firms to relocate existing facilities to foreign countries (impact on decisions to locate new facilities in foreign countries is covered in Section Five), on POTWs through reductions in pollutant-loading-based revenues, and on distributional equity and environmental justice. Each of these analyses are discussed in detail in the sections below.

8.1 ANALYSIS OF FOREIGN TRADE IMPACTS

Pharmaceutical products are traded in an international market, with producers and buyers located worldwide. Changes in domestic pharmaceutical production due to the Final Pharmaceutical Industry Effluent Guidelines might therefore affect the balance of trade. Exports might decrease as previously exported products are no longer manufactured, and imports might increase as domestic purchasers seek new sources of pharmaceuticals discontinued as a result of facility closures or firm failures.

These foreign trade effects are the focus of this section of the EA. The total change in value of U.S. pharmaceutical exports resulting from the guidelines is estimated. The significance of this change is then scrutinized by comparing it with the total value of current U.S. pharmaceutical exports. Ideally, the analysis would extend to consideration of changes in imports, as well as any additional export losses from facilities experiencing impacts short of closure, such as product line closures. Analysis of these issues, however, would require an international market model. This level of analysis is beyond the scope of the current analysis.

Sections 8.1.1 and 8.1.2 present the methodology used to estimate the change in the value of exports and evaluate the significance of this impact and the results of that analysis. Note that these impacts occur under the assumption that the pharmaceutical industry cannot or will not pass through costs to consumers, thus these impacts would reflect a decision on the part of the industry to absorb all costs of compliance and

thus would experience no price disadvantages in the international market. Section 8.2 investigates whether firms or facilities are likely to relocate to foreign countries due to the effluent guidelines and in that way affect the balance of trade.

8.1.1 Methodology

For facilities expected to close and that exported a portion of their pharmaceutical production in 1990, the value of 1990 pharmaceutical exports is estimated. The estimate for each facility is obtained directly from survey data: the total value of pharmaceutical shipments reported by the facility is multiplied by the percentage of pharmaceutical shipments exported, and these values are summed across closing facilities to obtain an estimate of the total value of U.S. pharmaceutical exports no longer produced. This value is then compared to the total value of U.S. pharmaceutical exports produced in 1990. The analysis assumes that none of the decreased production of exported pharmaceutical products is replaced by alternative U.S. products. This "worst-case" assumption is very conservative and is likely to overestimate the reduction in exports. If the impact on foreign trade is not significant in this worst-case scenario, then more realistic scenarios would also indicate no significant impacts. Likewise, increases in imports are assumed to be equivalent to the decline in exports (consistent with the zero cost-passthrough assumption used in the facility- and firm-level impact models). The existing balance of trade is then adjusted to reflect the increase in the value of imports and decline in the value of exports. A comparison of pre-and post-regulation trade balances will reveal the extent of the regulation's impact on the U.S. balance of trade.

8.1.2 Results

The impact of effluent guidelines on pharmaceutical exports and the U.S. balance of trade is negligible. As discussed in Section Five and Section Six, one facility is expected to close as a result of the selected options (under Baseline 3 only) and one single-facility firm is expected to close and fail. Neither of these facilities export any pharmaceutical products, thus EPA anticipates no impact from closures/failures on

the $5.7 billion (1991) total pharmaceutical industry exports.[1] Table 8-1 presents the results of this analysis. Note that no baseline analysis is performed because EPA expects no closure of facilities in the baseline.

8.2 EFFECTS ON PROFIT MARGINS AND THE LIKELIHOOD OF FOREIGN RELOCATIONS

EPA investigated baseline and postcompliance profit margins among the firms affected by the Final Pharmaceutical Industry Effluent Guidelines (including MACT standards impacts) to determine whether impacts on profitability might exert pressure on firms to relocate to foreign countries. A measure of impact on a firm is the extent to which profit margins are affected (although clearly this effect is not of the magnitude associated with closures and failures). Furthermore, it might be argued that firms with the means to relocate themselves or their facilities to foreign countries where environmental requirements might be less stringent might do so in response to a potential profit margin "squeeze." The detailed methodology and results of a profit margin analysis are presented below in Sections 8.2.1 and 8.2.2.

8.2.1 Methodology

EPA uses posttax EBIT (earnings before interest and taxes) divided by revenues as the measure of profit margin. The Agency uses posttax EBIT to allow for the different means by which various firms finance their capital, as recommended by Brealey and Meyers.[2] Only firms in the postcompliance analysis that do not fail postcompliance are analyzed here (baseline failures are dropped from the analysis; postcompliance failures also are dropped to avoid double counting impacts). EPA investigated median profit margins in each of the baselines and postcompliance relative to the three baselines. EPA also individually assessed firms where profit margins are expected to drop by more than 10 percent (for example where a 5 percent profit margin drops to below 4.5 percent). This assessment includes not only by how much profit margins drop, but the means these firms might have to relocate. Relocation to foreign countries entails not

[1] U.S. Department of Commerce. 1993. *U.S. Industrial Outlook: 1993.* Washington, DC: U.S. Government Printing Office.

[2] Brealey, Richard A., and Myers, Stewart C. 1996. *Principles of Corporate Finance*, Sixth Edition. New York: McGraw-Hill.

Table 8-1

Loss in Foreign Shipments for Selected Options
(1990 dollars)
Postcompliance Analysis

Facility Subcategory	Exports Lost	Total Exports *	Percent of Total
Direct Discharge			
A/C	$0	$695	0%
B/D	$0	$9,174,487	0%
Indirect Discharge			
A/C	$0	$478,207,957	0%
B/D	$0	$447,853,303	0%
Zero Discharge			
A/C	$0	$2,444,418	0%
B/D	$0	$845,906	0%
All Facilities			
TOTAL	$0	$938,527,152	0%

* These numbers reflect those foreign shipments projected to remain following the baseline analysis.

Note:
1. Analysis assumes no foreign shipments are lost for certified facilities.
2. Analysis excludes 12 facilities (1 A/C direct discharger, 1 B/D direct discharger, 1 A/C indirect discharger, 8 B/D indirect dischargers, and 1 A/C zero discharger) because of lack of financial data.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

only the means to physically move location, but the means to afford the transaction costs of relocating to a country if a firm currently has no operating experience there. Language and cultural barriers can effectively prevent small firms with limited resources from relocating. Total shipments of any firms likely to relocate are assessed against total exports, both in the affected industry and the broader pharmaceutical industry. EPA also assesses the impact of trade agreements and other barriers to a cheaper operation outside the environmental controls imposed by the United States that might further discourage relocation.

8.2.2 Results

Table 8-2 shows the median and ranges of aftertax profit margins under each of the three baselines after the costs of the effluent guidelines are considered and assuming no costs can be passed through to consumers. As the table shows, the median aftertax profit margin is a healthy 7.59 percent in Baseline 1. The median does not vary across all three baselines and across all three postcompliance scenarios. At most, from Baseline 1 through Postcompliance Scenario 3 (postcompliance against Baseline 3, which includes MACT standards costs), the median profit margin drops from 7.59 to 7.53 percent. Of course, individual firms can experience larger impacts than medians might suggest, so EPA also investigated the numbers of firms that might experience a reduction in profit margin of more than 10 percent (see Table 8-3 and Table 8-4). Table 8-3 presents the baseline profit margins by size of profit margins. As the table shows, many firms (over 50 percent, regardless of baseline) have profit margins in the range above 7 percent. The vast majority of these firms show nearly no impact throughout all baselines and postcompliance. Another 20 to 21 percent (depending on baseline) have profit margins in the 4 to 7 percent range. A further 13 to 14 percent have profit margins in the 2 to 4 percent range. Only 12 to 13 percent have profit margins in the less than 2 percent range either before or after compliance with the Final Pharmaceutical Industry Effluent Guidelines. Neither the Final Pharmaceutical Industry Effluent Guidelines nor the MACT standards rule appear to have very noticeable impacts on these ranges.

Table 8-4 investigates the more highly affected firms. EPA individually evaluated firms showing large changes in profit margins, defined here as a change in profit margin greater than 10 percent (calculated as a percent change in the percentage). As Table 8-4 shows, eight firms will have a change in profit margin of greater than 10 percent (one additional firm experiences a change greater than 10 percent postcompliance relative to Baseline 3). These firms therefore comprise a group of firms that will experience some impacts

Table 8-2

Profit Margin Median and Range for Firms Affected by the Final Pharmaceutical Industry Effluent Guidelines

	Median	Range	
		Minimum	Maximum
Baseline 1	7.59%	-54.01%	77.40%
Baseline 2	7.59%	-54.01%	77.40%
Baseline 3	7.59%	-54.19%	77.40%
Postcompliance 1	7.53%	-54.01%	77.40%
Postcompliance 2	7.53%	-54.01%	77.40%
Postcompliance 3	7.53%	-54.19%	77.40%

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

Table 8-3

Baseline and Postcompliance Profit Margins *

Profit Margin	Baseline 1				Baseline 2				Baseline 3			
	Baseline		Postcompliance		Baseline		Postcompliance		Baseline		Postcompliance	
	Number of Firms	Percent of Total	Number of Firms	Percent of Total	Number of Firms	Percent of Total	Number of Firms	Percent of Total	Number of Firms	Percent of Total	Number of Firms	Percent of Total
< 0%	9	7.0%	9	7.0%	9	7.0%	9	7.0%	9	7.0%	9	7.0%
0 - 1%	3	2.3%	3	2.3%	3	2.3%	3	2.3%	3	2.3%	3	2.3%
>1 - 2%	4	3.1%	4	3.1%	4	3.1%	4	3.1%	5	3.9%	5	3.9%
>2 - 4%	16	12.5%	17	13.3%	16	12.5%	17	13.3%	17	13.3%	18	14.1%
>4 - 7%	27	21.1%	27	21.1%	27	21.1%	27	21.1%	25	19.5%	25	19.5%
>7%	69	53.9%	68	53.1%	69	53.9%	68	53.1%	69	53.9%	68	53.1%
Total	128	100.0%	128	100.0%	128	100.0%	128	100.0%	128	100.0%	128	100.0%

* Out of firms in the postcompliance analysis.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

Table 8-4

Percentage Reduction in Profit Margin due to the Pharmaceutical Effluent Guidelines

Profit Margin	Total	Percentage Reduction in Profit Margin									
		0 - <5%		5 - <10%		10 - <20%		20 - <50%		>= 50%	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<7% Baseline profit margin	59	48	84.1%	4	6.8%	2	3.4%	2	3.4%	3	5.1%
>7% Baseline profit margin	69	66	95.7%	2	2.9%	1	1.4%	0	0.0%	0	0.0%
<7% Baseline profit margin	59	48	81.4%	4	6.8%	2	3.4%	2	3.4%	3	5.1%
>7% Baseline profit margin	69	66	95.7%	2	2.9%	1	1.4%	0	0.0%	0	0.0%
<7% Baseline profit margin	59	48	81.4%	3	5.1%	3	5.1%	2	3.4%	3	5.1%
>7% Baseline profit margin	69	66	95.7%	2	2.9%	1	1.4%	0	0.0%	0	0.0%

* Measured as (Postcompliance profit margin (%) - Baseline profit margin(%)) / Baseline profit margin (%).

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

short of firm failure as a result of the effluent guidelines (Table 8-5). A total of two of these nine firms also are counted as having some impacts in the indeterminate analysis in Section Six. The total number of distinct firms in both analyses sum to 14.

Furthermore, these nine firms may have the greatest motivation for relocating facilities outside the United States. EPA addresses these issues and investigates whether, even if the motive is there, the means are available to undertake a relocation.

As Table 8-5 shows, most of these firms are not likely to experience a large absolute change in profit margin (measured as baseline profit margin minus postcompliance profit margin). Only firm 8, which drops from a 12.16 percent profit margin to a 9.90 percent profit margin under Baseline 3 (note that this firm also appears as an affected firm in the indeterminate analysis), is appreciably affected under the three baselines. Six of the remaining firms' profit margins drop, in absolute (not percentage) terms, less than 1 percent. Two additional firms show a drop greater than 0.5 percent in absolute terms. When the leap from Baseline 1 to Postcompliance Scenario 3 is considered (the maximum impact from the combined rules), three firms experience an absolute drop in profit margins of more than 1 percent, with an additional three firms showing an absolute drop of more than 0.5 percent.

Many of these firms with large percentage and absolute drops in profit margin are unlikely to have the means to undertake a foreign relocation. The median assets of the group of 9 firms is $12.5 million, median working capital is $4.5 million, and median total equity is $7.6 million. Furthermore, the median foreign shipments value is $95,500 and the median percentage of foreign shipments to total shipments is 2 percent. Thus, this group is generally composed of small firms with little to no experience with foreign markets. The two largest firms (in terms of assets) in this group, that might be more able to find the means to relocate, have the smallest absolute change in profit margins (0.30 percent and 0.43 percent), which might limit their motivation to relocate, even though on a percentage change basis, the change is about 10 percent for both.

Several factors other than means and motivation might limit any incentive to relocate. First, many foreign countries, either on their own, or as a result of trade agreements such as the North American Free Trade Agreement, are becoming more aggressive with environmental controls. It is likely that where relocation might make sense (for example, close to major market areas such as Europe or the Far East) firms

Table 8-5

Profit Margins of Firms Showing Some Impact Short of Firm Failure

Firm ID	Baseline 1			Baseline 2			Baseline 3		
	Baseline Profit Margin	Postcompliance Profit Margin	Percent Change	Baseline Profit Margin	Postcompliance Profit Margin	Percent Change	Baseline Profit Margin	Postcompliance Profit Margin	Percent Change
1	5.01%	3.04%	-39.28%	5.01%	3.04%	-39.28%	5.01%	3.04%	-39.28%
2	2.73%	2.43%	-11.08%	2.73%	2.43%	-11.08%	2.64%	2.34%	-11.46%
3	0.88%	0.33%	-62.98%	0.88%	0.33%	-62.98%	0.88%	0.33%	-62.98%
4	-5.29%	-6.20%	-17.32%	-5.29%	-6.20%	-17.32%	-5.29%	-6.20%	-17.32%
5	4.70%	4.27%	-9.31%	4.70%	4.27%	-9.31%	3.81%	3.38%	-11.47%
6	12.16%	9.90%	-18.58%	12.16%	9.90%	-18.58%	11.89%	9.63%	-19.00%
7	3.99%	2.14%	-46.48%	3.99%	2.14%	-46.48%	3.99%	2.14%	-46.48%
8	-0.24%	-0.60%	-155.26%	-0.24%	-0.60%	-155.26%	-0.24%	-0.60%	-155.26%
9	0.82%	0.25%	-69.15%	0.82%	0.25%	-69.15%	0.79%	0.23%	-71.18%

Source: Section 308 Survey Data and the Pharmacutical Industry Facility and Firm Model, EPA, 1998.

may be faced, or may soon be faced, with some of the same environmental control issues, and these controls might be even more expensive outside of the United States (for example, if pollution control equipment must be imported from the United States, transportation costs alone would make pollution control equipment more expensive).

Despite the general lack of motivation and the potential lack of means and other barriers to relocation discussed above, some firms might consider relocating facilities. If the ten firms identified above, which have perhaps the greater motivation to relocate, were to relocate their facilities, the impact on the balance of trade can be represented by the total domestic and international shipments of pharmaceuticals by these firms. These domestic and international shipments combined total $263.7 million, of which only about $4 million are international shipments. The potential for loss in foreign shipment is only 0.001 percent of the $305 billion of all foreign shipments by the U. S. in 1991, and the potential for increase in imports is only 0.04 percent of the $732 billion in imports in 1991.[3] Thus, even in the very unlikely event that these firms do relocate some or all of their pharmaceutical facilities, the impacts on trade and the balance of payments are negligible.

8.3 IMPACTS ON POTWS

Comments on the proposed rule raised the possibility that if pharmaceutical facilities no longer send the same level of pollutant loadings to POTWs, revenues to POTWs could suffer. According to EPA's development document, however, EPA is promulgating pretreatment standards for 24 volatile organic compounds for all subcategories and ammonia for subcategories A and C. The Agency expects that the reduction in the BOD discharged to POTWs as the result of compliance with PSES for these pollutants to be minimal. As a result, EPA believes that any reduction in revenue to POTWs that charge industrial users, subject to PSES, will be insignificant. Since many of these pollutants are highly volatile and are volatilized in the POTWs' primary units before they can be biodegraded, EPA believes that the final PSES should not have any substantial effect on the variable operating costs of POTWs as well.

[3] U.S. Bureau of the Census. 1997. *Statistical Abstract of the United States*. Washington, DC: U.S. Government Printing Office.

Even if BOD loads to POTWs were to drop substantially, there are a number of mitigating factors to consider. First, the numbers of POTWs that receive a large portion of their flow from pharmaceutical facilities must be determined. Second, the way in which POTWs set their fees must be considered. Third, even if a POTW receives a large portion of flow from affected pharmaceutical facilities, and it sets fees on the basis of pollutant loadings or concentrations rather than raw volume, effects on both revenues and costs must be considered. These issues and supporting analyses are discussed below.

8.3.1 Methodology

EPA investigated the prevalence of POTWs with a large proportion (10 percent of industrial flow or more) of flow received from pharmaceutical firms. In 1988, the Agency undertook the National Sewage Sludge Survey, which asked, among other things, the amount of flow from various types of industries to the respondent POTWs. This statistically valid survey of the universe of POTWs operating secondary and above treatment processes, although somewhat dated, should still provide a reasonable estimate of the prevalence of POTWs with a high percentage of flow from the pharmaceutical industry.

The other two considerations—how many POTWs set rates on the basis of pollutant loadings or concentrations, and impacts on costs—are addressed qualitatively in the results section below.

8.3.2 Results

Using the National Sewage Sludge Survey, EPA determined that only a few POTWs received more than 10 percent of their industrial flow from pharmaceutical facilities in 1988. Table 8-6 presents the results of EPA's search for potentially highly affected POTWs.[4] In all other cases, pharmaceutical flow is less than 10 percent of total industrial flow. It is important to note that the six POTWs listed here statistically represent about 45 POTWs nationwide. In particular, Rochester and Wade Hampton are statistically representative of

[4] None of the information in the NSSS is CBI, since these are publicly owned entities.

Table 8-6

POTWs With Substantial Pharmaceutical Wastewater Flow
(>10 percent of total industrial flow)

Survey ID	POTW Name	POTW Authority	Percentage of Industrial Flow Attributed to Pharmaceutical Industry	Percentage of Total Revenues Attributable to Industry User Fees
35-23-207	Rochester STP*	City of Rochester, MI	51.76%	97.45%
16-32-263	Passaic Valley Treatment Plant	Passaic Valley Sewerage, Newark, NJ	14.07%	27.47%
33-35-303	Orangetown DPW*	Town of Orangetown, NY	56.25%	25.20%
35-42-389	Wade Hampton Plant	WCRSA, Greenville, SC	35.82%	24.97%
26-32-267	Rahway Valley STP	Rahway Valley, NJ	41.51%	15.75%
24-15-104	NSSD-Clavely Rd. STP	North Shore SD, Gurnee, IL	13.97%	14.18%

*Pharmaceutical flow is also 27 percent (Rochester) and 21 percent (Orangetown) of total flow (not just industrial flow)

Source: U.S. EPA, 1988 National Sewage Sludge Survey.

20 POTWs each. (Passaic, Rahway, and NSSD represent themselves only, and Orangetown represents two POTWs, statistically).[5]

It is possible that among these 45 POTWs, the pharmaceutical industry might contribute a sizeable amount to POTW revenues, but the way in which these POTWs set rates also needs to be considered. Generally, POTWs might set rates by total volume of flow, by amount of pollutants load (for example, on the basis of BOD or some other pollutant), or on the basis of flow at or above a certain pollutant concentration. POTWs also might mix these rate setting strategies. For example one rate might be set for volume, with a surcharge for volume over a certain BOD concentration. Only POTWs where the major portion of the fee collected from the user is set on the basis of pollutant concentration or load would see a marked decline in revenues if pollutant loads or concentrations dropped substantially.

On the other hand, reductions in pollutant loads or concentrations from users often result in measurable costs savings. A portion of a POTW's variable costs depends on the load handled by the facility. For example, higher BOD content may require greater power usage stemming from the greater need for aeration to keep the wastewater and sewage sludge treatment processes aerobic, if an aerobic process is used. Higher TSS levels result in larger amounts of sewage sludge generated, with higher costs of disposal. Higher concentrations of pollutants can also lead to a greater need for treatment chemicals such as coagulants or clarifying chemicals. So even if the POTW loses some revenues, it saves some costs.

Even if revenue losses exceed costs savings, POTWs will, one way or another, pass through these impacts to their users. Most of the POTWs that are at all likely to be affected by potential reductions in loads from pharmaceutical firms are located in urban areas and are likely to have large numbers of users over which to spread any fee increases or other costs. By the time the revenue losses are translated to a cost-per-user basis, any small impact from the effluent guidelines will be difficult to measure. For example, the entire $245,000 loss of revenues that the commenter estimated would occur at Passaic Valley would amount to

[5] Presented in this table is one of the POTWs cited in the comments to the proposal, Passaic Valley. Note that although the commenter argues that losses in revenues to Passaic will be $254,000, the commenter does not note Passaic's annual revenues. In 1988, these revenues totaled about $56 million, so this loss, if it occurred, would amount to only 0.45 percent of Passaic's revenues (assuming revenues have remained constant over the intervening years).

almost nothing on a per-user basis, if it materialized at all, given that some costs savings might be experienced and given the huge number of users in Newark, NJ, and its environs.

Thus EPA concludes that (1) impacts on BOD levels will be minimal, (2) relatively few POTWs will be potentially affected even if BOD or other pollutant loads or concentrations are reduced substantially, (3) fewer still are likely to have rate structures sensitive to declines in pollutant loads or concentrations, (4) some of these will experience costs savings of, perhaps, a similar magnitude, (5) where a noticeable difference between revenues lost and costs savings occurs, an impact directly on the POTW will probably not occur, since impacts will be passed to users, and (6) any impacts on users, once spread over many users, will be negligible.

8.4 DISTRIBUTIONAL EQUITY AND ENVIRONMENTAL JUSTICE

8.4.1 Analysis of Distributional Impacts

Up to this point, the EA has been conducted assuming zero cost passthrough (i.e., that facilities cannot raise pharmaceutical prices in an effort to recoup regulatory costs). As pointed out in Section Three, however, the assumption that pharmaceutical manufacturers act as pure price takers in perfectly competitive markets probably would not hold true in most cases. Many markets for specific drugs are characterized by monopolistic or oligopolistic conditions in which manufacturers exercise considerable control over drug prices. The zero cost passthrough model was employed nonetheless because product-specific demand elasticity data are lacking, and because this assumption tends to overstate facility impacts rather than understate them (i.e., it provides for a worst-case scenario of facility- and firm-level impacts).

Conversely, the assumption that facilities will bear the entire cost of incremental regulatory costs might understate the economic impacts on consumers of pharmaceuticals. If the more realistic assumption that manufacturers will raise pharmaceutical prices in response to increased regulatory costs is employed, then one needs to consider who will be affected by these price increases and whether high drug prices will affect certain demographic groups more than others. For example, the elderly account for a very large portion of all drug use. This group, therefore, might be particularly hard hit by increases in drug prices. It might be reasonable to assume that the uninsured population will also be particularly hard hit by increases in drug

prices because they have no immediate financial recourse and might have to make difficult decisions between pharmaceuticals and other daily necessities. Ultimately, state and federal governments might bear the costs of increased drug prices through Medicaid, Medicare, and other health insurance programs.

This section first investigates the extent to which drug prices could rise assuming perfectly inelastic demand. Given perfectly inelastic demand, the EA calculates the rise in drug prices as the ratio of total compliance costs to total cost of pharmaceutical production in the affected facilities (e.g., if compliance costs are 1 percent of pharmaceutical production costs, then drug prices of all drugs at the affected facilities are assumed to rise by 1 percent). The analysis then investigates the impacts of increased drug prices on various demographic groups such as the elderly, the population living under the poverty level, disadvantaged minorities, the uninsured, and state and federal governments. In the absence of any quantitative data on price elasticities and existing drug prices, the discussion is necessarily qualitative in nature. The discussion assumes that pharmaceutical manufacturers are able to pass through all of the increased regulatory costs associated with the various waste water treatment options, including all MACT costs, where they occur.

8.4.2 Increases in Drug Prices

Table 8-7 shows compliance costs (including costs of the MACT standards rule), as a percentage of total pharmaceutical costs by regulatory option. The average (median) ratio for each subcategory (calculated on a facility-by-facility ratio basis) ranges from 0.002 to 0.3 percent. For all the selected regulatory options combined, the median ratio of compliance costs to total pharmaceutical costs by facility is approximately 0.01 percent. Table 8-7 also shows the distribution of the number of facilities by compliance costs to pharmaceutical costs. As can be seen, 31 facilities (12 percent of all facilities in this analysis) would incur compliance costs greater than 1 percent but less than 10 percent of total pharmaceutical production costs, and seven facilities (3 percent of all facilities) would incur compliance costs greater than 10 percent of total pharmaceutical costs under the selected options (including MACT standards costs). One quarter of all facilities would experience no increase in total pharmaceutical production costs as a result of the effluent guidelines plus MACT standards costs.

Reliable data on total U.S. pharmaceutical production costs are not available. Thus, the EA cannot precisely compute compliance costs as a percentage of total U.S. pharmaceutical production costs.

Table 8-7

Compliance Costs as a Percentage of Total Pharmaceutical Production Costs, by Facility (includes MACT standards costs)

Regulatory Option	Compliance Costs/Total Costs										
	0.0%		>0.0% - 0.1%		>0.1% - 1.0%		>1.0% - 10.0%		>10%		
	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	Median Ratio
Selected Options											
BAT-A/C (with BPT)	1	7%	2	14%	6	43%	4	29%	1	7%	0.191%
BPT-B/D only	3	33%	1	0%	4	44%	0	0%	0	0%	0.034%
PSES-A/C	8	9%	18	21%	13	15%	19	22%	4	5%	0.295%
PSES-B/D	38	25%	59	39%	11	7%	8	5%	2	1%	0.002%
All Facilties											
All	50	19%	80	31%	34	13%	31	12%	7	3%	0.009%

Note:
1. Analysis excludes certified facilities and zero dischargers.
2. Analysis also excludes six additional facilities (one A/C direct discharger, two A/C indirect dischargers, and three B/D indirect dischargers) because of lack of financial data.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

Nevertheless, it is clear that if worst-case compliance costs average 0.01 percent of the total pharmaceutical production costs of the regulated sector, this ratio would be significantly lower if compliance costs were compared to pharmaceutical production costs for the entire industry.

8.4.3 Impacts on Specific Demographic Groups

Although in the aggregate, the potential overall increase in drug prices attributable to increased regulatory costs is minuscule, the potential increase in specific drug prices might have a significant impact on certain demographic groups. As noted above, seven facilities will experience compliance costs in excess of 10 percent of total pharmaceutical manufacturing costs. If the drugs produced by these facilities are unique (i.e., protected from direct competition either through patents or a lack of close substitutes) then these facilities might be able to increase the price of their drugs in order to offset compliance costs. Table 8-8 presents the result of an examination of the products produced by facilities that incur compliance costs greater than 10 percent of total pharmaceutical production costs and presents which groups predominantly use the types of products made at these facilities. A total of 40 products were identified as products potentially subject to substantial price increases out of a total of more than 110,000 pharmaceutical products manufactured each year.[6]

Because of confidentiality, the name or type of drug is not presented. The unknown category deals with products that might be inputs to drugs rather than drugs themselves (i.e., they are primarily reported as chemical names).

As Table 8-8 shows, children (including infant and adolescents), women, and the elderly are likely to be the major consumers of many of these products. According to Health Insurance Association of America,[7] the groups least likely to have health insurance are Hispanics (31.2 percent of whom lack health insurance), young adults 16-24 years of age (20.5 percent of whom lack health insurance), and African Americans (17.5 percent of whom lack health insurance); African Americans, Hispanics, and children are most likely to be

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[6] As cited in RTI, 1993. *Economic Analysis of Effluent Guidelines Regulations for the Pharmaceutical Industry.* Draft Report. Contract No. 68-C8-0084. Research Triangle Park, NC: RTI.

[7] Health Insurance Association of America, 1991. *Source Book of Health Insurance Data.*

Table 8-8

Disproportionate Users of Potentially Highly Affected Products

	Total Numbers of Affected Products	Infants, Children, or Adolescents	The Elderly	Young Adults/Adult Women	Middle-Aged Women	African-Americans	Other	Unknown
Number of Products	40	15	28	13	4	3	3	18
Percentage of All Affected Products	100%	38%	70%	33%	10%	8%	8%	45%

Source: Overton, V., and A. Desilets. Demographics of the Major Users of Selected Drugs. Memorandum dated June 18, 1998 (confidential business information).
Note: Each product might be used disproportionately by several groups.

covered by government insurance, and African Americans, Hispanics, and the elderly are least likely to have insurance related to employment. Government insurance programs tend to spend less on drugs and other medical nondurables than do private insurers, according to the same source, and about 93 percent of people with work-related medical insurance have some type of drug insurance.

When all these factors are accounted for, it appears that those who lack any health insurance, those who are covered by government insurance, and those who are covered by nonwork-related medical insurance might be least likely to have drug coverage. This group would include: Hispanics, African Americans, the elderly, young adults (16-34), and children (under 16). When the predominant consumers of the products expected to be affected by potentially sizeable price increases are compared to the groups most likely to lack drug insurance, young adult women, children, and the elderly are likely to be the most affected by potential price increases, if such increases can be passed through to consumers.

Because, on average, any potential price increases are likely to be very low (0.01 percent on average), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers, should be minimal.

8.4.4 Environmental Justice

Impacts on environmental justice should be minimal. As noted above, any price increases on drugs will be very small, and impacts on disadvantaged groups such as the poor and certain minority groups will be minimal. Furthermore, many of these groups will benefit from the Final Pharmaceutical Industry Effluent Guidelines. The benefits of the Final Pharmaceutical Industry Effluent Guidelines, discussed more fully in Section Ten, are expected to be widely dispersed, and will include recreational anglers, POTWs, and thus the general public, and persons consuming fish from the reaches of surface water affected by pharmaceutical effluent. Since the persons most likely to benefit from lower levels of contaminants in fish tend to be subsistence anglers, not recreational anglers, these benefits might accrue to persons in lower socioeconomic groups and/or Native Americans. Also, since children of subsistence anglers are likely to be the most vulnerable of all these groups to any pollutants taken up by fish, this is another group most likely to accrue health benefits.

A large number of the surveyed pharmaceutical facilities (10.5 percent) are located in Puerto Rico, which is substantially poorer than the United States as a whole. The per capita income of Puerto Rico is $7,009 ($1993), in contrast to the lowest U.S. per capita income, by state, of $14,475 ($1993) for Mississippi.[8] The regulation of the pharmaceutical industry will result in a cleaner environment, both water and air, which will directly benefit all persons, but the greatest benefit might accrue to lower socioeconomic groups that often live near major urban manufacturing facilities such as those regulated by the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Thus many of those who might bear the costs of the regulation (however small), including children and those in lower socioeconomic groups, might also be those who gain the most benefit from the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

[8]Per capita income sources: http://www.pr-eda.com and http://www.census.gov

SECTION NINE

FINAL REGULATORY FLEXIBILITY ANALYSIS

9.1 INTRODUCTION

This section examines the projected effects of the costs from incremental pollution control on small entities as required by the Regulatory Flexibility Act (RFA, 5 U.S.C. 601 et seq., Public Law 96-354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). EPA is not bound by the requirements of SBREFA because this amendment became effective after the Pharmaceutical Industry Effluent Guidelines were proposed. Nevertheless, EPA has followed guidance on the analyses recommended under the RFA as amended. This section determines impacts on small entities resulting from the Final Pharmaceutical Industry Effluent Guidelines, separately from and together with, the MACT standards rule.

The RFA acknowledges that small entities have limited resources and makes the regulating federal agency responsible for avoiding burdening such entities unnecessarily. Pursuant to the RFA, EPA has prepared a final regulatory flexibility analysis (FRFA).[1] Section 9.2 reviews the steps suggested in Agency guidance materials to determine whether a regulatory flexibility analysis is required and how to identify significant impacts on small businesses. Section 9.3 responds to the regulatory flexibility analysis components required for a final rule by Section 604 of the RFA. Section 9.4 is a detailed description of the small business economic analysis performed for the proposed regulation.

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[1] The preparation of an FRFA for a final rule does not legally foreclose certifying no significant impact for the final rule; see U.S. EPA, 1997. *Interim Guidance for Implementing the Small Business Regulatory Enforcement Fairness Act and Related Provisions of the Regulatory Flexibility Act.* February 5.

9.2 INITIAL ASSESSMENT

The following passage lists the initial assessment steps suggested in current EPA guidance.[2] The steps are posed as a series of questions and answers:

- Is the Rule Subject to Notice-and-Comment Rulemaking Requirements?

  The Effluent Limitations Guidelines and Standards for the Pharmaceutical Industry is subject to notice-and-comment rulemaking requirements.

- Profile of Affected Entities

  EPA prepared a profile of the regulated universe of entities; see Section Three and Section Three of the EIA for the proposal (the universe and profile has not changed significantly since proposal).

- Will the Rule Affect Small Entities?

  Yes, EPA has identified a maximum of 145 small entities subject to the rule.

- Will the Rule Have an Adverse Economic Impact on Small Entities?

  EPA has determined that some small entities might incur costs for incremental pollution control as a result of the rule. EPA examines the impacts of these additional costs in Section 9.4, as well as in this initial assessment section.

EPA can perform an initial assessment of the potential for a rule to result in adverse impacts on small entities. This initial assessment can indicate whether the rule requires a regulatory flexibility analysis to be performed. EPA's guidance for performing this initial assessment[3] suggests the use of a revenue test (annual compliance costs as a percentage of annual revenues) to determine whether a rule will have a significant impact on a substantial number of small entities. If the number or percentage of firms exceeding certain benchmarks is low (for example, if fewer than 100 firms incur costs that are greater than 1 percent of annual revenues and if fewer than 100 firms incur costs that exceed 3 percent of annual revenues), the rule is considered to meet qualifications allowing the EPA Administrator to certify the rule as having no significant

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[2] U.S. EPA, 1992. *EPA Guidelines for Implementing the Regulatory Flexibility Act.* U.S. Environmental Protection Agency, Office of Policy, Planning, and Evaluation, April; and U.S. EPA, 1997. *Op. cit.*

[3] U.S. EPA, 1997, *Op. cit.*

impact on a substantial number of small entities. As Table 9-1 shows, only 4 small firms or 3.2 percent of all small firms that could be analyzed will incur annual compliance costs that are greater than 1 percent of annual revenues and no firms will incur costs exceeding 3 percent of annual revenues. Even when MACT Baseline 3 costs are added in, only 6 firms (4.8 percent) will incur annual compliance costs that are greater than 1 percent of revenues and 1 firm (0.8 percent) will incur annual costs greater than 3 percent. This firm, however, incurs only the costs of the MACT standards rule (costs for the Final Pharmaceutical Industry Effluent Guidelines are zero), and therefore is not considered to be an affected firm in this RFA. The Final Pharmaceutical Industry Effluent Guidelines are thus considered a Category 1 rule. Category 1 rules may be certified as having no significant impact on a substantial number of small entities without performing a FRFA. To further support this finding, however, EPA follows with a FRFA in Sections 9.3 and 9.4, below.

9.3 REGULATORY FLEXIBILITY ANALYSIS COMPONENTS

Section 604 of the RFA requires that an FRFA must:

- state the need for and objectives of the rule.
- summarize the significant issues raised by public comments on the initial regulatory flexibility analysis (IRFA) and the Agency's assessment of those issues, and describe any changes in the rule resulting from public comments.
- describe the steps the Agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of the applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant regulatory alternatives to the rule considered by the Agency which affect the impact on small entities was rejected.
- describe/estimate the number of small entities to which the rule will apply or explain why no such estimate is available.
- describe the projected reporting recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirements of the rule.

The following sections address these issues.

Table 9-1

SBREFA Revenue Test Analysis

Impact Category Costs/Revenue	Final Pharmaceutical Industry Effluent Guidelines		Effluent Guidelines plus MACT Standards Rule	
	Number of Small Firms *	Percentage of All Small Firms	Number of Small Firms	Percentage of All Small Firms
> 1 Percent	4	3.2%	6	4.8%
> 3 Percent	0	0.0%	1	0.8%

* Small firms are defined as those with less than 750 employees.
Note: Three small firms were left out of the analysis due to insufficient revenue data.

9.3.1 Need for and Objectives of the Rule

The rule is being proposed under the authority of Sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act, 33 U.S.C. Sections 1311, 1314, 1316, 1317, 1318, and 1361. Under these sections, EPA is setting effluent guidelines and standards for the control of discharge of pollutants for the Pharmaceutical Industry Point Source Category. The regulations also are being proposed pursuant to a Consent Decree entered in NRDC et al. v. Reilly (D.D.C. No. 89-2980, January 31, 1992), and are consistent with EPA's latest Effluent Guidelines Plan under Section 304(m) of the CWA (see 61 FR 52582, October 7, 1996).

The objective of the CWA is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." To assist in achieving this objective, EPA issues effluent limitations guidelines; pretreatment standards, and new source performance standards for industrial dischargers. Sections 301(b)(1) and 304(b)(1) authorize EPA to issue BPT effluent limitations guidelines; Section 304(b)(4) authorizes EPA to issue BCT guidelines for conventional pollutants; Sections 301(b)(2)(E) and 304(b)(2) authorize EPA to issue BAT guidelines to control nonconventional and toxic pollutants; Section 306 authorizes EPA to issue NSPS for all pollutants; and Sections 304(g) and 307(b) authorize EPA to issue PSES and PSNS for all pollutants.

9.3.2 Significant Issues Raised by Public Comments on the IFRA

Three issues were raised in public comments on the IFRA. One commenter suggested that "adding pilot-scale operations to the [rule] will leave small biotech firms economically disadvantaged." EPA, however, will not revise the scope of applicability for the rule to include research (Subcategory E) facilities. The same commenter states that "EPA has assumed that capital costs for control equipment will be offset by rolling costs back to consumers purchasing drugs currently on the market....[Start up biotech companies do not have any drugs on the market to offset these costs...." EPA, in fact, did not assume that costs could be passed on to consumers, and all impacts identified in this EA, other than those on consumers, are estimated assuming that costs cannot be passed through. Another commenter states that "[impact of the regulation

biases disproportionately on small firms." EPA disagrees. The impacts of the rule are minimal and, as discussed below, are not disproportionate. See EPA's comment response document.[4]

9.3.3 Steps the Agency Has Taken To Minimize Significant Economic Impact on Small Entities

The Agency has taken no steps to minimize significant economic impacts on small entities, because very few small entities are expected to experience significant economic impacts. The only alternatives that are less costly to small entities than those selected for the final rule are no-action alternatives, which are, for the most part, not considered to meet the objectives of the Clean Water Act. Although a no-action alternative was chosen for one subcategory (BAT for BD directs), this decision was made neither on the basis of economic achievability nor on the basis of minimizing significant economic impacts on small entities.

9.3.4 Describe/Estimate the Number of Small Entities To Which the Rule Will Apply

EPA estimates that a maximum of 145 out of 190 (76 percent) pharmaceutical firms subject to the rule might be classified as small under SBA definitions. Small firms are defined in 13CFR Part 121 either by their employment size or by their revenues. As discussed in Sections Two and Three of this report, the major SIC categories affected by the Final Pharmaceutical Industry Effluent Guidelines are SICs 2833, 2834, 2835, and 2836. In SIC 2833 and 2834, small firms are defined as those employing 750 or fewer persons; in SIC 2835 and 2836, those employing 500 or fewer persons are defined as small. For simplicity, and as done in the Initial Regulatory Flexibility Analysis (IRFA) at proposal, this FRFA designates all pharmaceutical firms as small if they employ fewer than 750 persons. These firms and their facilities were profiled in Section Three of this EA.

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[4] U.S. EPA, 1998. *Comment Response Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*.

9.3.5 Describe Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

Under current law, before this rule, as well as after implementation of this rule, all affected firms are subject to monitoring and permitting requirements.

9.4 IMPACTS OF THE FINAL RULE ON SMALL ENTITIES

EPA has selected facility closures and firm failures as identifying measures of significant impact in this FRFA. As discussed in Sections Five and Six of this EA, one facility owned by a multifacility firm will close (although only if MACT standards costs are included), one single-facility firm will fail and close, two single-facility firms will fail but will probably not close (i.e., they will lose their financial independence), and one multifacility firm will fail or must sell (but not close) one or more of its facilities. All of the firms associated with these impacts are small firms. Given that 76 percent of all affected firms are small, this result is not disproportionate. If exact proportionality of impacts were to have occurred, we could expect out of five significantly affected firms that four would have been small. The difference between four significantly affected small firms out of five total affected firms (large or small) and five significantly affected small firms out of five total affected firms is minimal.

SECTION TEN

COST AND BENEFITS OF THE FINAL PHARMACEUTICAL INDUSTRY EFFLUENT GUIDELINES AND MACT STANDARDS RULE

10.1 INTRODUCTION

10.1.1 Requirements of Executive Order 12866 and the Unfunded Mandates Reform Act (UMRA)

This section has been prepared to comply with Executive Order 12866, which requires federal agencies to assess the costs and benefits of each significant regulatory action. Although the Final Pharmaceutical Industry Effluent Guidelines by themselves are not considered a significant regulatory action, the combined effect of the effluent guidelines and the MACT standards rule could be considered to meet the definition in the executive order. The principal requirements of the Executive Order are that the Agency perform an analysis comparing the benefits of the regulation to the costs that the regulation imposes, that the Agency analyze alternative approaches to the rule, and that the need for the rule be identified. Wherever possible, the costs and benefits of the rule are to be expressed in monetary terms. To address the analytical requirements, as specified by the Executive Order, this section discusses the social costs of the rule in Section 10.2, pollutant reductions in Section 10.3, the benefits of the rule in Section 10.4, and the comparison of costs and benefits in Section 10.5. The industry has been profiled in Section Three of this EA, the technology options and regulatory alternatives were presented in Section Four, and impacts of the rule and its alternatives were discussed in Sections Five through Nine. Section 10.1.2, below, presents the need for the regulation.

This section also has been prepared to comply with Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, which establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local and tribal governments and the private sector. Under section 202 of UMRA, EPA generally must prepare a written statement, including a cost-benefits analysis, for proposed and final rules with "federal mandates" that may result in expenditures to state, local and tribal governments, in the aggregate, or the private sectors, of $100 million or more in any one year. Additionally, Executive Order 12875, Enhancing the Intergovernmental Partnership, aims to reduce unfunded mandates and provide

increased flexibility for states and local governments to utilize policy approaches. This executive order supplements but does not supplant Executive Order 12866.

Before promulgating an EPA rule for which a written statement is needed, section 205 of UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that might significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Although some states and local governments will incur costs to implement the Final Pharmaceutical Industry Effluent Guidelines, these costs to governments will not exceed the thresholds established by UMRA and, in general, the effluent guidelines will make it easier for POTWs to establish limits on discharge to POTWs. Although EPA does not believe the rule imposes significant or unique effects on small governments, under sections 203 and 205 of the UMRA, EPA has consulted with state and local governments.

EPA has determined that the final rule will not, by itself, contain a federal mandate that might result in expenditures of $100 million or more for the private sector in any one year, but the combination of the final rule and the MACT rule will be greater than $100 million in pretax 1997 dollars. Accordingly, EPA has prepared the written statement required by section 202 of the UMRA. This and previous sections of the EA constitute this statement: Sections Five and Six of the EA identify impacts to firms and facilities covered by the rule, and Sections Seven and Eight identify output, employment, and other secondary impacts of the rule.

EPA does not believe that there will be any disproportionate budgetary effects of the proposed rule on any particular areas of the country, particular types of communities, or particular industry segments. EPA's basis for this finding is the analysis of economic impacts, which is presented in the previous sections of this EA.

Furthermore, EPA has selected the "least costly, most cost-effective, and least burdensome alternative" for BPT, BCT, BAT, NSPS, PSES, and PSNS that is consistent with the CWA. This satisfies section 203 of UMRA. As part of the rulemaking, EPA has identified and considered a reasonable number of regulatory alternatives, as described in Section Four of this EA. EPA's selection from among various options is consistent with the requirements of the UMRA in terms of costs, cost-effectiveness, and burden.

10.1.2 Need for the Regulation

Executive Order 12866 requires that the Agency identify the need for the regulation being proposed. The discharge of pollutants directly or indirectly into surface water poses a threat to human health and the environment. Risks from these discharges include the potential for cancer and other adverse noncancer health effects and degradation of the environment. These discharges also might cause interference or inhibition problems at POTWs. This section discusses: (1) the reasons the marketplace does not provide for adequate pollution control absent appropriate incentives or standards; (2) the environmental factors that indicate the need for additional pollution controls for this source category; and (3) the legal requirements that dictate the necessity for and timing of this regulation.

The need for pretreatment standards for this source category arises from the failure of the marketplace to provide the optimal level of pollution control desired by society. Correction of such a market failure can require federal regulation. OMB defines market failure as the presence of externalities, natural monopolies, and inadequate information.[1] This section addresses the category of externalities, which is the category of market failure most relevant to the general case of environmental pollution.

[1] OMB, 1996. *Economic Analysis of Federal Regulation Under Executive Order 12866*, January 11.

The concept of externalities partially explains the discrepancy between the supply of pollution control provided by owners and operators of pollution sources and the level of environmental quality desired by the general population. The case of environmental pollution can be classified as a negative externality because it is an unintended byproduct of production that creates undesirable effects on human health and the environment.

In making production decisions, owners and operators will consider only those costs and benefits that accrue to them personally (i.e., internalized costs and benefits). However, the cost of environmental pollution is not borne solely by the creators of the pollution because all individuals in the polluted area (which can be quite large since pollution usually does not stay in one place) must share the social cost of exposure to the pollution. Therefore, although owners and operators might be the creators of pollution, they do not necessarily bear the full costs of the pollution. Government regulation is an attempt to internalize the costs of pollution.

If the people affected by a particular pollution source could negotiate with the party responsible for that source, the parties could negotiate among themselves to reach an economically efficient solution. The solution would be efficient because it would involve only those individuals who are affected by the pollution. In effect, the solution would involve the trading of pollution and compensation among the owner or operator and the people affected by that pollution.

Individual negotiation often does not occur in an unregulated market, however, because of high transaction costs, even if trade among the affected parties would be beneficial to all parties involved. For the majority of environmental pollution cases, the costs of identifying all the affected individuals and negotiating an agreement among those individuals is prohibitively high. Another problem preventing negotiations from taking place is that our current market system does not clearly define liability for the effects of pollution.

In the case of environmental quality, an additional problem is the public nature of this “good.” Environmental quality is a public good because it is predominantly nonexcludable and nonrival. Individuals who willingly pay for reduced pollution cannot exclude others who have not paid from also enjoying the benefits of a less polluted environment. Because many environmental amenities are nonexcludable, individuals utilize but do not assume ownership of these goods and therefore will not invest adequate resources in their protection. The result is that in the absence of government intervention, the free market will

not provide public goods, such as a clean environment, at the optimal quantity and quality desired by the general public.

In the case of the pharmaceutical industry, the result of the market's failure to promote water pollution control is that pollution of the nation's surface waters and ground waters is not controlled to the optimal level. This industry releases significant amounts of pollutants to surface waters through wastewater treatment plants. Despite state and local regulatory programs, many areas are still adversely affected by pollutant discharges by this industry. Section 10.3 discusses in detail the impacts of the regulation on reducing pollutants entering surface water.

Both UMRA and Executive Order 12866 require the statutory authority for the rule to be cited. The regulation is proposed under the authorities of sections 301, 304, 306, 307, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendment of 1972, 33 U.S.C. 1251 et seq., as amended by the Clean Water Act of 1987, Pub. L. 100-4, also referred to as the CWA or the Act).

10.2 SOCIAL COSTS OF THE RULE

In the Development Document (as discussed in earlier sections of this EA), EPA developed costs of the Final Pharmaceutical Industry Effluent Guidelines based on the costs of labor, equipment, materials, and other resources needed for regulatory compliance. Although these costs are a major portion of the costs to society of the proposed regulation, they are not the only costs. The costs investigated earlier in this document reflect the costs from the perspective of the regulated community, not from the perspective of the whole society. In this section, EPA estimates the social cost of the regulation, including the costs to society in terms of forgone state and federal tax revenues, for the resources needed to comply with the regulation. Other cost categories, including administrative (permitting) costs and unemployment benefits administration costs are not significant, but also are estimated. EPA also adds in the social costs associated with the MACT standards rule.

10.2.1 Cost Categories

Social costs of a regulation comprise costs that go beyond just the facilities' costs of purchasing, installing, and operating pollution control equipment (compliance costs). Some of these additional costs are monetary, but many are nonmonetary. Additional monetary costs include the federal and state subsidies in the form of a tax shield, costs of administering a regulation (permitting costs), and the costs of administering unemployment benefits (unemployment benefits themselves are transfer payments, not a cost), including the cost of relocating displaced workers. Additional nonmonetary costs could include the inconvenience, discomfort, and time loss associated with unemployment, possible losses in consumer and producer surpluses, and possible slowdown in the rate of innovation if the industry bears large compliance costs. This section discusses in more detail the types of costs that may be components of a social cost estimate. Section 10.2.3 presents the estimates for the cost categories to which EPA could assign monetary values.

Compliance Costs

The largest component of social cost is the cost to industry of complying with the regulation. These costs have been discussed in Section Four, but are incomplete for the purposes of this section. The costs presented in Section Four are the posttax costs (the costs to industry after compliance costs have been expensed or depreciated for tax purposes and income taxes have been paid on earnings). These posttax costs reflect the tax shield on compliance costs. The tax shield is the cost to the state and federal governments of subsidizing, in effect, the cost of the regulation. Tax shields are also a cost to society and must be included in the estimate of social costs. EPA uses the social discount rate of 7 percent, as recommended by OMB,[2] as used in the economic impacts analysis (see Section Four).

Because the pretax costs include no cost passthrough assumptions, no consumer surplus is lost. Additionally, the pretax cost will incorporate the loss in producers' surplus. The pretax costs of compliance thus include losses in consumer and producer surplus.

[2] OMB, 1996. *Op. cit.*

These costs have not been adjusted either by baseline closures/failures of facilities or firms. The analysis in Section Six shows that all baseline failing firms own viable facilities (i.e., they do not close) postcompliance. As discussed in Section Six, EPA expects them to be sold and operated, thus they would incur compliance costs. Additionally, no nonindependent facilities (those owned by multifacility firms) are assumed to close in the baseline but are evaluated at the firm level. Since the firms can afford to operate these facilities postcompliance, EPA assumes all nonindependent facilities will install pollution control equipment.

Costs also are not adjusted downward for postcompliance closures, even though one facility is assumed to close, thus would not install or operate this equipment. The compliance cost to this facility totals $2.7 million annually for both Final Pharmaceutical Industry Effluent Guidelines and MACT standards costs. EPA considers this cost a reasonable upper estimate of the cost to the firm of closing this facility.[3] The firm will choose, to the extent possible, the less expensive of the two choices: install and operate pollution control or close the facility.

Administrative Costs

Implementing the Final Pharmaceutical Industry Effluent Guidelines will require that permitting authorities incur costs for writing, monitoring, and enforcing permits under the regulation. These costs of administering the regulation will add to the resource cost of regulatory compliance and are part of the total social cost of the regulation. Section 10.2.2.2 presents the methodology and estimates for administrative costs of the proposed rule.

Worker Dislocation Costs

EPA also investigates costs associated with worker dislocations as an additional component of social costs. These costs comprise the value to workers of avoiding unemployment and the costs of administering unemployment (the unemployment benefits themselves, as discussed above are transfer payments, not costs).

[3] These liquidation costs include legal fees, broker fees, etc.

Nonmonetary Costs

Several other cost categories are not discussed in detail in the social cost estimate section. The first is loss of consumer and producer surpluses. As noted earlier, the use of the total pretax cost of compliance provides a reasonable upper limit estimate of the social cost of the regulation for pollution control including losses of consumer and producer surpluses. The cost estimate section also does not discuss the cost associated with a slowdown in the rate of innovation. Monetizing the loss associated with a slowdown in the rate of innovation is a very difficult task. Although there might be some small impact on the rate of innovation if they did not have to allocate resources to meeting the requirements of the proposed Final Pharmaceutical Industry Effluent Guidelines, a noticeable effect is relatively unlikely because compliance costs are not large relative to industry revenues, comprising at most (including costs of the MACT standards rule) only about 0.3% of those revenues on average.

10.2.2 Estimate of Social Costs

10.2.2.1 Costs of Compliance

As Table 10-1 shows, the social (pretax) cost of compliance for the selected options range from $0 to $36.1 million annually ($1990), depending on option. The selected options have an annualized pretax cost of $49.4 million ($1990). When costs of the MACT standards rule are included (for all facilities, not just those affected by the effluent guidelines) pretax costs total $96.8 million ($1990).

10.2.2.2 Administrative Costs

EPA uses the methodology developed for the Metal Products and Machinery (MP&M) effluent guidelines to estimate administrative costs of this rule.[4] From analysis of the Section 308 Survey database, EPA estimates that 286 facilities that are covered by this rule, of which 38 are direct dischargers that

[4] U.S. EPA, 1995. *Regulatory Impact Analysis of Proposed Effluent Limitations Guidelines and Standards for the Metal Products and Machinery Industry (Phase I).* Appendix E. Office of Water (EPA 821-R-95-023), April.

Table 10-1

Costs of Compliance
(1990 dollars)

Regulatory Option	Compliance Costs
BPT-A/C	$2,016,233
BPT-B/D	$1,121,232
BAT-A/C	$2,926,352
BAT-B/D *	$0
PSES-A/C	$36,131,966
PSES-B/D	$7,166,657
Total Selected Options	**$49,362,441**
MACT wastewater emission control costs	$8,714,027
Total MACT for effluent guidelines analysis facilties	$40,325,058
Total MACT for effluent guidelines analysis facilities + Selected Options	**$89,687,499**
Total MACT, all facilities	$47,446,953
Total MACT + Selected Options	**$96,809,394**

* BAT-B/D costs would have been $0.3 million had this option been selected.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

currently have a permit in place. Another 248 facilities are indirect dischargers, of which only 35 reported they currently do not have a permit and only 1 provided no information. Therefore EPA expects a total of 36 facilities are subject to regulation and currently discharge to a POTW without a federally or locally mandated permit. For the purposes of the estimates here, EPA assumes that all indirect dischargers will incur incremental permitting costs because the facilities that do have permits from their local POTWs are assumed to require the same attention as those that do not. The existing permits vary widely in form and function, but are generally not of the scope mandated by the federal pretreatment standard permit system. EPA estimated the incremental administrative costs of administering the regulation for these facilities in the following five categories:

- Permit application and issuance (developing and issuing permits, providing technical guidance, conducting public hearings, and conducting evidentiary hearings);
- Inspection (conducted for initial permit development or subsequent inspection);
- Monitoring (sampling and analyzing permittee's effluent, reviewing and recording permittee's compliance self-monitoring reports, receiving, processing, and acting on a permittee's noncompliance reports, and reviewing a permittee's compliance schedule report for a permittee in compliance and a permittee not in compliance);
- Repermitting; and
- Enforcement

Although other administrative costs (e.g., identifying facilities to be permitted, providing technical guidance to permittees in years other than the first year of the permit, and repermitting a facility in significant noncompliance) might be incurred infrequently by some POTWs, EPA believes the above five categories capture the bulk of the administration burden of the proposed regulation. Note, however, that some of the administrative costs might be offset by cost savings at POTWs that need to develop local limits, since it is less time consuming for POTWs to write permits when national limits have been set. These cost savings have not been estimated.

EPA's analysis of the administrative costs of the Final Pharmaceutical Industry Effluent Guidelines is based on the estimated length of time and cost needed to perform each of the administrative functions listed above and the frequency of administrative activities for the facilities subject to regulation. The information on length of time and cost for the administrative functions was originally compiled as part of the analysis of

administrative costs for the proposed Metal Products and Machinery Industry (MP&M) Phase 1 regulation, conducted in 1995. The original sources of this data included: Information Collection Request analyses; a resource planning model used by EPA; an informal survey of six POTWs and three state permitting officials, and discussions with EPA Regional Office and headquarters permitting staff.[5] EPA believes the time and cost of administrative functions for implementing the Final Pharmaceutical Industry Effluent Guidelines are not likely to differ materially from those for the MP&M regulation and hence the estimates developed for the MP&M regulation are used in this analysis.

Permitting activities and their associated costs and assumptions are listed in Table 10-2. The Final Pharmaceutical Industry Effluent Guidelines are concentration-based, but are incorporated into a mass-based permit limit based on average facility flow. EPA uses cost estimates for mass-based permits as a conservative estimate of the costs to prepare a permit. Generally, this approach will overstate costs.

The administrative costs assumptions specific to the Final Pharmaceutical Industry Effluent Guidelines include:

- EPA does not expect the administrative costs to increase as a result of the Final Pharmaceutical Industry Effluent Guidelines for facilities that are direct dischargers. Administrative costs for these subcategories may decrease because the technical guidance provided by EPA as a component of the rule may provide information to the permitting authorities that is likely to reduce the research required to develop permits. These costs savings have not been estimated and are not included in the administrative costs of the Final Pharmaceutical Industry Effluent Guidelines.

- EPA assumes the 241 indirect dischargers (286 total facilities minus 38 direct dischargers and 7 zero dischargers) may require some effort to permit, although the vast majority hold some type of permit. EPA uses the cost to develop a mass-based permit for a previously unpermitted facility, which should produce a somewhat high estimate of the cost to permit the indirect discharging facilities.

[5] For more detailed information on the methodology and data sources for this analysis, see U.S. EPA, 1995. *Op. cit.* EPA adjusted the costs presented in this report from 1989 dollars to 1990 dollars by the change in the Producer Price Index (Council of Economic Advisors, 1997. *Economic Report of the President*).

Table 10-2

Administrative Cost Components and Frequency per Facility

Activity	Frequency	Percent of Facilities for Which Activity is Required	Cost Estimates (1990 dollars)		
			Low	Average	High
Develop and issue a mass-based permit at a previously unpermitted facility	1 time	100%	$327	$917	$1,497
Provide technical guidance	1 time	100%	$38	$187	$337
Conduct a public hearing	1 time	5%	$1,123	$1,576	$1,871
Conduct an evidentiary hearing	1 time	5%	$9,357	$13,099	$16,841
Permittee Inspection Flow <= 1 million gal/yr Flow > 1 million gal/yr	every 5 years annual	100%	$52	$475	$898
Sample and Analyze Permittee's Effluent Flow <= 1 million gal/yr Flow > 1 million gal/yr	every 5 years annual	100%	$304	$727	$1,402
Review and Data Entry of Permitttee's Self-monitoring Reports Flow <= 1 million gal/yr Flow > 1 million gal/yr	every 5 years annual	100%	$28	$38	$47
Receive, Process, and Act on a Permittee's Non-compliance Reports Flow <= 6.25 million gal/yr Flow > 6.25 million gal/yr	annual	10% 30%	$112	$131	$150
Review a Compliance Report for a Permittee Meeting Milestones Flow <= 6.25 million gal/yr Flow > 6.25 million gal/yr	1.5 reports a year/3 years	90% 95%	$7	$9	$12
Review a Compliance Schedule Report for a Permittee Not Meeting Milestones	1.5 reports a year/3 years	20%	$112	$150	$187
Minor Enforcement Action, e.g., Issue an Administrative Order	annual	10%	$299	$599	$898
Minor Enforcement Action, e.g., Impose an Administrative Fine	annual	5%	$2,994	$4,491	$5,988
Repermit	every 5 years	100%	$38	$281	$524

Sources: U.S. EPA, 1995. *Op. cit.*, and Council of Economic Advisors, 1997. *Economic Report of the President*.

The frequency and percent of facilities associated with certain permitting activities varies by the amount of process wastewater generated (see EPA, 1995, *op. cit.*, for details). Table 10-3 summarizes the facility counts by flow category.

Table 10-4 summarizes the number of facilities incurring costs by activity for a 16-year period following promulgation of the rule. The 16-year period is consistent with the period used in the cost-annualization model for the compliance costs. These costs are then annualized over the 16-year period at the 7 percent real social discount rate. EPA used the information in Tables 10-2 and 10-3 to calculate low, average, and high estimates for administrative costs of the rule. The estimated average annualized cost of $206,585 ($1990) is used as the social cost of administering the rule (see Table 10-5). Even with the conservative assumptions used in the analysis, administrative costs are less than 1 percent of the estimated compliance costs.

10.2.2.3 Unemployment Costs

EPA does not calculate an additional cost of unemployment based on the willingness of workers to pay to avoid unemployment (although the Agency does compute the cost of administering unemployment benefits to workers in facilities projected to close post compliance later in this section) for the following reason. It is important to recall that EPA estimates the cost of the regulation as the cost to all facilities—both those that would stay open and incur compliance costs and those that are estimated to close and not incur these costs. The social cost of worker displacement is reflected in workers' willingness to pay to avoid unemployment. If the workers' willingness to pay to avoid unemployment exceeds the pollution control cost (assuming the ability of labor and management to negotiate a solution, e.g., wage cuts for workers), then pollution control equipment would be installed and operated at the facility. If the pollution control cost exceeds the willingness (or the ability) of workers to pay to avoid facility closure, then retaining that cost in the industry-wide estimate provides an upper bound for the social cost of the proposed regulation, including the cost of worker dislocation. In other words, the social costs of worker dislocation should not be added to the estimated cost of the regulation when the costs of compliance at facilities that close due to the regulation are included in that estimate, because to do so would be double-counting. Therefore, EPA assumes that the cost of compliance at facilities that are estimated to close as a result of the proposed regulation is the upper limit estimate of workers' willingness to pay to avoid unemployment (plus any liquidation costs; see

Table 10-3

Facility Counts by Flow Subcategory

Flow Category	Number of Facilities		
	A/C Indirects	B/D Indirects	Total
Less than 1 million gallons per year	87	153	240
Greater than 1 million gallons per year	1	0	1
Total	88	153	241

Source: Section 308 Survey Data.

Table 10-4

Facility Counts by Year and Administrative Activity

Activity	Facility Counts															
	Year Relative to Rule Promulgation															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Issue a permit	241															
Provide technical guidance	241															
Conduct a public hearing	12															
Conduct an evidentiary hearing	12															
Inspect a permitee	241	1	1	1	1	241	1	1	1	1	241	1	1	1	1	241
Sample effluent	241	1	1	1	1	241	1	1	1	1	241	1	1	1	1	241
Review self-monitoring report	241	1	1	1	1	241	1	1	1	1	241	1	1	1	1	241
Process NCR	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24
Review CSR: compliance	217			217			217			217			217			217
Review CSR: non-compliance	48			48			48			48			48			48
Repermit						241					241					241
Issue an administrative order	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24
Enforcement seeking penalty	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

Note: All facilities are assumed permitted in the first year. The compliance schedule is assumed to span three years. See Table 10-2 for assumptions.

Table 10-5

Administrative Costs of the Regulation
(1990 dollars)

Estimate	Annualized Administrative Cost of the Proposed Rule
Low	$95,179
Average	$206,585
High	$333,295

Source: Tables 10-2, 10-3, and 10-4.

discussion above). Thus, EPA does not add a willingness to pay to avoid unemployment to the costs of worker dislocations.

On the other hand, unemployment benefits administration costs are an additional social cost that must be considered. One recent RIA has provided information on unemployment benefits administration costs, noting that they are about $100 per laid-off worker (a one-time cost).[6] The maximum number of worker dislocations estimated in Section Seven are those estimated based on output losses in the U.S. economy. The selected options are associated with total maximum, nationwide employment losses of 1,014 FTEs (associated with the Final Pharmaceutical Industry Effluent Guidelines only) or 1,842 FTEs (including losses associated with the MACT standards rule). Note that this estimate overstates total dislocations, since many of these losses are offset by sizable gains (see Section Seven), some which may occur within the same facility (e.g., production worker becomes pollution control equipment operator). Furthermore, these losses are really hours lost, not necessarily workers lost. These losses therefore most likely substantially overstate actual job losses. EPA, however, conservatively uses the 1,014 (without the MACT standards rule) to 1,842 FTEs (with the MACT standards rule) to mean jobs. EPA estimates that maximum unemployment benefits administration costs for the options will range from $2,300 to $74,200, depending on the subcategory. Over the 16-year time frame of the analysis and at a 7 percent discount rate, this cost by subcategory ranges from $240 to $7,860 per year, for a total of $10, 730 annually over all selected options.

Note that a multifacility firm might consider increased unemployment insurance premiums in its decision to close a facility. Because compliance costs for facilities owned by multifacility firms are already included in the estimate of social costs, to the extent such increased premiums are used to pay for the costs of administering unemployment benefits, adding these costs to the compliance costs of facilities that close postcompliance will overstate costs.

10.2.2.4 Total Social Costs

Table 10-6 presents the total social costs associated with each of the selected options. These costs range from $1.1 million to $36.2 million ($1990) annually, depending on the option. The selected options are

[6] U.S. EPA, 1995. *Op. cit.*

Table 10-6

Social Costs of Compliance
(thousands of 1990 dollars)

Regulatory Option	Compliance Costs	Administrative Costs	Unemployment Benefits Administration Costs	Total Costs
BAT-A/C (with BPT)	$4,942.59	$0.00	$1.07	$4,943.66
BAT-B/D (with BPT)	$1,121.23	$0.00	$0.24	$1,121.48
PSES-A/C	$36,131.97	$76.02	$7.86	$36,215.84
PSES-B/D	$7,166.66	$130.57	$1.56	$7,298.78
Total Selected Options	$49,362.44	$206.59	$10.73	$49,579.77
Total MACT, effluent guidelines facilities	$40,325.06	NA *	$8.77	$40,333.83
Total MACT, all facilities	$47,446.95	NA *	$10.32	$47,457.27
Total MACT, effluent guidelines + Selected Options	$89,687.50	$206.59	$19.50	$89,913.59
Total MACT, all facilities + Selected Options	$96,809.39	$206.59	$21.06	$97,037.04

* Administrative costs were not calculated for MACT but are not expected to be small relative to the total costs of the two rules combined.

associated with annual total social costs of $49.6 million ($1990). When MACT standards costs are added in, annual social costs total $97.0 million ($1990).

10.3 POLLUTANT REDUCTIONS

Tables 10-7 through 10-10 present the results of EPA's loadings estimates by option (see EPA's Development Document for how the loadings and loadings reductions were calculated). The table presents raw loads, baseline loads, and postcompliance loads, along with load reductions in both pounds and in pounds-equivalent (PE), which are calculated on the basis of toxic weighting factors (TWFs). TWFs allow EPA to weight the pounds removed by the relative toxicity of each pollutant for which a removal is measured. EPA's *Cost-Effectiveness Analysis for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Industry* discusses in detail how PEs are calculated. The selected options are associated with postcompliance removals of 16.2 million pounds and 373,198 PEs from waters of the United States. Note that these removals do not include the air removals associated with the MACT standards rule. These removals amount to an additional 48 million pounds.[7]

10.4 ASSESSMENT OF BENEFITS

10.4.1 Introduction

This section presents an assessment of the annual, nationwide benefits of the Final Pharmaceutical Industry Effluent Guidelines, as well as the benefits expected to accrue from the corresponding MACT standards rule. This assessment considers the benefits expected to result from implementation of these rules due to reductions in effluent loadings and air emissions from four sources (wastewater for the Final Pharmaceutical Industry Effluent Guidelines and wastewater, process vents, storage tanks, and equipment leaks emission controls for the MACT standards rule). A variety of human health, environmental, and POTW benefits might result from these reductions. The benefit categories considered in this assessment of

[7] U.S. EPA, 1998. *National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production.*

Table 10-7

Industry Loads and Removals by Pollutant
BAT-A/C Facilities

Pollutant Code	Pollutant Name	Removals (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	1.08E+00	0
CHEM3	Acetonitrile	1,146	8.50E-05	0
CHEM9	Ammonia-N	800,913	2.70E-03	2,162
CHEM10	Amyl Acetate, n-	1,616	8.60E-04	1
CHEM11	Pentanol, 1- (amyl alcohol)	52,174	1.60E-04	8
CHEM12	Aniline	0	1.50E+00	0
CHEM15	Benzene	0	4.80E-01	0
CHEM25	Methyl ethyl ketone	0	2.90E-04	0
CHEM26	Butyl acetate, n-	0	3.10E-03	0
CHEM27	Butanol, 1- (n-butyl alcohol)	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	3.20E-05	0
CHEM35	Chlorobenzene	0	1.10E-02	0
CHEM37	Trichloromethane (chloroform)	4,080	1.00E-01	408
CHEM48	Dichlorobenzene, 1,2-	0	1.20E-02	0
CHEM51	Dichloroethane, 1,2-	147	1.50E+00	221
CHEM55	Diethylamine	0	2.80E-04	0
CHEM60	Dimethylacetamide, N,N-	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	3,712	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	1.80E-01	0
CHEM70	Ethanol	195,517	5.80E-04	113
CHEM71	Ethyl acetate	87,223	7.60E-04	66
CHEM77	Ethylene glycol	0	8.40E-05	0
CHEM79	Formaldehyde	0	2.30E-03	0
CHEM80	Formamide	0	0.00E+00	0
CHEM84	Heptane, n-	0	6.20E-02	0
CHEM87	Hexane, n-	241	3.10E-02	7
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	0	2.10E-03	0
CHEM94	Isopropanol (2-propanol)	165,987	5.60E-03	930
CHEM95	Isopropyl Acetate	286	6.90E-05	0
CHEM96	Isopropyl Ether	0	6.10E-04	0
CHEM97	Methanol	712,931	3.30E-04	235
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	0	1.60E-01	0
CHEM102	Dichloromethane (methylene chloride)	41,905	1.20E-01	5,029
CHEM103	Methyl formate (formic acid, methyl ester)	8,437	8.90E-06	0
CHEM105	Methyl isobutyl ketone	14,462	2.10E-03	30
CHEM113	Petroleum Naptha	0	6.70E-02	0
CHEM114	Phenol	8,995	2.83E-02	254
CHEM115	Polyethylene Glycol 600	0	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	2.70E-05	0
CHEM118	Acetone	17,832	1.60E-03	29
CHEM124	Pyridine	0	1.60E-01	0
CHEM129	Tetrahydrofuran	31,821	7.00E-03	223
CHEM130	Toluene	8,042	6.40E-03	51
CHEM136	Triethylamine	0	1.50E-04	0
CHEM139	Xylenes	2,581	4.30E-03	11
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0.00E+00	0
	Totals	2,160,048		9,780

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

Table 10-8

Industry Loads and Removals by Pollutant
BAT-B/D Facilities

Pollutant Code	Pollutant Name	Removals (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	1.08E+00	0
CHEM3	Acetonitrile	0	8.50E-05	0
CHEM9	Ammonia-N	0	2.70E-03	0
CHEM10	Amyl Acetate, n-	0	8.60E-04	0
CHEM11	Pentanol, 1- (amyl alcohol)	0	1.60E-04	0
CHEM12	Aniline	0	1.50E+00	0
CHEM15	Benzene	0	4.80E-01	0
CHEM25	Methyl ethyl ketone	0	2.90E-04	0
CHEM26	Butyl acetate, n-	0	3.10E-03	0
CHEM27	Butanol, 1- (n-butyl alcohol)	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	3.20E-05	0
CHEM35	Chlorobenzene	0	1.10E-02	0
CHEM37	Trichloromethane (chloroform)	0	1.00E-01	0
CHEM48	Dichlorobenzene, 1,2-	0	1.20E-02	0
CHEM51	Dichloroethane, 1,2-	0	1.50E+00	0
CHEM55	Diethylamine	0	2.80E-04	0
CHEM60	Dimethylacetamide, N,N-	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	0	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	1.80E-01	0
CHEM70	Ethanol	7,477	5.80E-04	4
CHEM71	Ethyl acetate	0	7.60E-04	0
CHEM77	Ethylene glycol	0	8.40E-05	0
CHEM79	Formaldehyde	171	2.30E-03	0
CHEM80	Formamide	0	0.00E+00	0
CHEM84	Heptane, n-	0	6.20E-02	0
CHEM87	Hexane, n-	0	3.10E-02	0
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	0	2.10E-03	0
CHEM94	Isopropanol (2-propanol)	14,646	5.60E-03	82
CHEM95	Isopropyl Acetate	0	6.90E-05	0
CHEM96	Isopropyl Ether	0	6.10E-04	0
CHEM97	Methanol	0	3.30E-04	0
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	0	1.60E-01	0
CHEM102	Dichloromethane (methylene chloride)	0	1.20E-01	0
CHEM103	Methyl formate (formic acid, methyl ester)	0	8.90E-06	0
CHEM105	Methyl isobutyl ketone	0	2.10E-03	0
CHEM113	Petroleum Naptha	0	6.70E-02	0
CHEM114	Phenol	0	2.83E-02	0
CHEM115	Polyethylene Glycol 600	46	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	2.70E-05	0
CHEM118	Acetone	0	1.60E-03	0
CHEM124	Pyridine	0	1.60E-01	0
CHEM129	Tetrahydrofuran	0	7.00E-03	0
CHEM130	Toluene	0	6.40E-03	0
CHEM136	Triethylamine	0	1.50E-04	0
CHEM139	Xylenes	0	4.30E-03	0
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0.00E+00	0
	Totals	22,339		87

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

Table 10-9

Industry Loads and Removals by Pollutant
PSES-A/C Facilities

Pollutant Code	Pollutant Name	Removals (lbs/yr)	POTW Removal Efficiency (%)	Removals After POTW (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	50%	0	1.08E+00	0
CHEM3	Acetonitrile	0	0%	0	8.50E-05	0
CHEM9	Ammonia-N	1,425,793	82%	259,494	2.70E-03	701
CHEM10	Amyl Acetate, n-	294,153	83%	50,594	8.60E-04	44
CHEM11	Pentanol, 1- (amyl alcohol)	0	83%	0	1.60E-04	0
CHEM12	Aniline	0	80%	0	1.50E+00	0
CHEM15	Benzene	120,896	19%	98,047	4.80E-01	47,063
CHEM25	Methyl ethyl ketone	0	83%	0	2.90E-04	0
CHEM26	Butyl acetate, n-	412,547	83%	70,958	3.10E-03	220
CHEM27	Butanol, 1- (n-butyl alcohol)	0	80%	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	81%	0	3.20E-05	0
CHEM35	Chlorobenzene	84,094	18%	69,042	1.10E-02	759
CHEM37	Trichloromethane (chloroform)	45,219	1%	44,812	1.00E-01	4,481
CHEM48	Dichlorobenzene, 1,2-	16,376	78%	3,553	1.20E-02	43
CHEM51	Dichloroethane, 1,2-	546	77%	124	1.50E+00	186
CHEM55	Diethylamine	61,644	67%	20,466	2.80E-04	6
CHEM60	Dimethylacetamide, N,N-	0	79%	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	83%	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	79%	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	0	95%	0	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	75%	0	1.80E-01	0
CHEM70	Ethanol	110	89%	12	5.80E-04	0
CHEM71	Ethyl acetate	1,693,800	83%	291,334	7.60E-04	221
CHEM77	Ethylene glycol	0	96%	0	8.40E-05	0
CHEM79	Formaldehyde	0	85%	0	2.30E-03	0
CHEM80	Formamide	0	67%	0	0.00E+00	0
CHEM84	Heptane, n-	17,502	37%	11,061	6.20E-02	686
CHEM87	Hexane, n-	1,133,860	37%	716,599	3.10E-02	22,215
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	29,737	73%	8,088	2.10E-03	17
CHEM94	Isopropanol (2-propanol)	11	81%	2	5.60E-03	0
CHEM95	Isopropyl Acetate	9,426	83%	1,621	6.90E-05	0
CHEM96	Isopropyl Ether	9,280	83%	1,596	6.10E-04	1
CHEM97	Methanol	22	80%	4	3.30E-04	0
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	978,930	15%	832,091	1.60E-01	133,135
CHEM102	Dichloromethane (methylene chloride)	677,934	15%	577,600	1.20E-01	69,312
CHEM103	Methyl formate (formic acid, methyl ester)	23,283	83%	4,005	8.90E-06	0
CHEM105	Methyl isobutyl ketone	254,906	81%	48,942	2.10E-03	103
CHEM113	Petroleum Naptha	0	80%	0	6.70E-02	0
CHEM114	Phenol	0	95%	0	2.83E-02	0
CHEM115	Polyethylene Glycol 600	0	96%	0	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	88%	0	2.70E-05	0
CHEM118	Acetone	2,234,971	83%	373,240	1.60E-03	597
CHEM124	Pyridine	0	0%	0	1.60E-01	0
CHEM129	Tetrahydrofuran	91,062	83%	15,663	7.00E-03	110
CHEM130	Toluene	640,348	36%	411,104	6.40E-03	2,631
CHEM136	Triethylamine	374,837	83%	64,472	1.50E-04	10
CHEM139	Xylenes	22,140	20%	17,624	4.30E-03	76
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0%	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0%	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0%	0	0.00E+00	0
	Totals	10,653,427		3,992,148		282,614

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

Table 10-10

Industry Loads and Removals by Pollutant
PSES-B/D Facilities

Pollutant Code	Pollutant Name	Removals (lbs/yr)	POTW Removal Efficiency (%)	Removals After POTW (lbs/yr)	Toxic Weighting Factor	PE Removals
CN-	Cyanide	0	50%	0	1.08E+00	0
CHEM3	Acetonitrile	0	0%	0	8.50E-05	0
CHEM9	Ammonia-N	0	82%	0	2.70E-03	0
CHEM10	Amyl Acetate, n-	810,977	83%	139,488	8.60E-04	120
CHEM11	Pentanol, 1- (amyl alcohol)	0	83%	0	1.60E-04	0
CHEM12	Aniline	0	80%	0	1.50E+00	0
CHEM15	Benzene	0	19%	0	4.80E-01	0
CHEM25	Methyl ethyl ketone	0	83%	0	2.90E-04	0
CHEM26	Butyl acetate, n-	0	83%	0	3.10E-03	0
CHEM27	Butanol, 1- (n-butyl alcohol)	0	80%	0	1.70E-03	0
CHEM29	Methyl-2-propanol, 2- (tert-butyl alcohol)	0	81%	0	3.20E-05	0
CHEM35	Chlorobenzene	0	18%	0	1.10E-02	0
CHEM37	Trichloromethane (chloroform)	0	1%	0	1.00E-01	0
CHEM48	Dichlorobenzene, 1,2-	0	78%	0	1.20E-02	0
CHEM51	Dichloroethane, 1,2-	0	77%	0	1.50E+00	0
CHEM55	Diethylamine	0	67%	0	2.80E-04	0
CHEM60	Dimethylacetamide, N,N-	0	79%	0	2.09E-06	0
CHEM62	N,N-Dimethylaniline	0	83%	0	8.30E-02	0
CHEM64	Dimethylformamide, N,N-	0	79%	0	2.40E-06	0
CHEM66	Dimethyl sulfoxide	0	95%	0	1.65E-06	0
CHEM67	Dioxane, 1,4-	0	75%	0	1.80E-01	0
CHEM70	Ethanol	0	89%	0	5.80E-04	0
CHEM71	Ethyl acetate	11,639	83%	2,002	7.60E-04	2
CHEM77	Ethylene glycol	0	96%	0	8.40E-05	0
CHEM79	Formaldehyde	0	85%	0	2.30E-03	0
CHEM80	Formamide	0	67%	0	0.00E+00	0
CHEM84	Heptane, n-	0	37%	0	6.20E-02	0
CHEM87	Hexane, n-	0	37%	0	3.10E-02	0
CHEM93	Methyl propanal, 2- (isobutyraldehyde)	0	73%	0	2.10E-03	0
CHEM94	Isopropanol (2-propanol)	300	81%	58	5.60E-03	0
CHEM95	Isopropyl Acetate	217,733	83%	37,450	6.90E-05	3
CHEM96	Isopropyl Ether	0	83%	0	6.10E-04	0
CHEM97	Methanol	0	80%	0	3.30E-04	0
CHEM101	Methoxyethanol, 2- (methyl cellosolve)	0	15%	0	1.60E-01	0
CHEM102	Dichloromethane (methylene chloride)	785,175	15%	668,969	1.20E-01	80,276
CHEM103	Methyl formate (formic acid, methyl ester)	0	83%	0	8.90E-06	0
CHEM105	Methyl isobutyl ketone	0	81%	0	2.10E-03	0
CHEM113	Petroleum Naptha	0	80%	0	6.70E-02	0
CHEM114	Phenol	1	95%	0	2.83E-02	0
CHEM115	Polyethylene Glycol 600	0	96%	0	5.60E-05	0
CHEM117	Propanol, 1- (n-propanol)	0	88%	0	2.70E-05	0
CHEM118	Acetone	1,520,984	83%	254,004	1.60E-03	406
CHEM124	Pyridine	0	0%	0	1.60E-01	0
CHEM129	Tetrahydrofuran	0	83%	0	7.00E-03	0
CHEM130	Toluene	0	36%	0	6.40E-03	0
CHEM136	Triethylamine	0	83%	0	1.50E-04	0
CHEM139	Xylenes	0	20%	0	4.30E-03	0
CHEMBOD	Biochemical Oxygen Demand 5-day	0	0%	0	0.00E+00	0
CHEMCOD	Chemical Oxygen Demand	0	0%	0	0.00E+00	0
CHEMTSS	Total Suspended Solids	0	0%	0	0.00E+00	0
	Totals	3,346,808		1,101,971		80,807

Source: U.S. EPA, 1998. Cost-Effectiveness Analysis of Final Effluent Limitations Guidelines and Standards for Existing and New Sources for the Pharmaceutical Industry.

the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are identified below. Specifically, this assessment addresses the following:

- Human health and agricultural benefits due to reductions in emissions to air of ozone precursors (i.e., reductions in volatile organic compounds [VOC] emissions)
- Human health benefits due to reductions in excess cancer risk
- Ecological and recreational benefits (environmental) due to improved water quality, including intrinsic benefits
- Benefits from reductions in interference and passthrough problems, improvements in worker health, and reductions in analytical costs at POTWs
- Human health benefits due to reductions in systemic and other risks, such as risk of developmental effects or individual organ toxicity

For the first three benefit categories, sufficient information is available to monetize the benefits of the final rules. The dollar magnitude of the benefits for the other two benefit categories cannot be quantified. EPA selected pollutants of concern if they met the following criteria: (1) they were found in treatable concentrations at a number of facilities; (2) they had discharge loadings greater than 3,000 pounds per year; (3) they were treatable by technology; and (4) they were quantified by an existing approved analytical method. Pollutants meeting these criteria were included in the modeling performed for the environmental assessment. A fifth selection criterion was used to identify pollutants to be regulated. This criterion required that at least 1,000 pounds per year of a pollutant be estimated to be removable from receiving streams as a result of the Final Pharmaceutical Industry Effluent Guidelines. This assessment also includes estimates for those benefits that would accrue if only regulated pollutants are considered. The methodology and data used in the estimate of all benefits, as well as the limitations of the analyses, are described in detail in the *Environmental Assessment of the Final Industry Guidelines for the Pharmaceutical Manufacturing Industry* (Environmental Assessment Report, U.S. EPA, 1998).

10.4.2 Reductions in Emissions of Ozone Precursors

10.4.2.1 Description of Benefits and Overall Approach

This assessment of the benefits from reductions in emissions of ozone precursors due to the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule considers benefits derived from evaluating ozone air quality changes. The following sections present the results of the assessment of the benefits associated with reductions in VOC emissions and the adverse environmental impacts associated with increased emissions of sulfur dioxide (SO_2) and particulate matter (PM). Benefits are estimated using the methodology and data summarized in the November 5, 1997, OAQPS memo titled, "Benefits-Transfer Analysis for Pulp and Paper." The methodology is based on the recently published benefits analysis provided in U.S. EPA, 1997, *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule*. It is briefly discussed, and the results of the analyses are summarized. Details are available in the previously mentioned references, as well as in the Environmental Assessment Report.

Controlling VOC emissions is beneficial because some VOCs are precursors to ground-level ozone, which negatively affects human health and the environment. The technology selected for controlling VOC emissions (steam stripping) requires the consumption of energy. Increased energy consumption results in increased emissions of PM and SO_2. These byproducts of increased energy use can cause adverse environmental impacts. Therefore, EPA has assessed the benefits of reduced VOC emissions and impacts of increased PM and SO_2 emissions as described in the following sections. In effect, EPA subtracts the impacts of increased emissions of PM and SO_2 from the benefits associated with the control of VOCs.

10.4.2.2 Valuation of Benefits from Final Pharmaceutical Industry Effluent Guidelines

VOC Analysis

This assessment estimates that the Final Pharmaceutical Industry Effluent Guidelines will reduce VOC emissions from wastewater (at an estimated 50 facilities) in nonattainment areas alone by 1,254 Mg per year and in all areas by 3,608 Mg per year (see the Environmental Assessment Report). The estimate of the range of the value of a unit reduction in VOC emissions in 1990 dollars ranges from $489 per Mg (does not

include mortality effects associated with ozone exposure) to $2,212 per Mg (includes mortality effects).[8] The estimated annual monetized benefits resulting from reductions in VOC emissions (not including adverse impacts of byproduct emissions of PM and SO_2) range from $0.6 to $8.0 million ($1990). These results are summarized in Table 10-11.

PM Analysis

EPA estimates that the Final Pharmaceutical Industry Effluent Guidelines will result in an *increase* in PM emissions by 20 Mg per year (Environmental Assessment Report). The estimated value of a unit increase in PM emissions in 1990 dollars is $10,823 per Mg.[9] Therefore, EPA estimates that the annual monetized adverse environmental impacts resulting from increases in PM emissions due to this final rule are $216,000 ($1990).

SO_2 Analysis

EPA also estimates that the Final Pharmaceutical Industry Effluent Guidelines will result in an *increase* in SO_2 emissions of 52.1 Mg (51.8 Mg, eastern United States and 0.3 Mg, western United States) (Environmental Assessment Report). The estimate of the range of the value of a unit increase in SO_2 emissions in 1990 dollars is $4,860 to $10,763 per Mg of SO_2 for the eastern United States; and $3,516 to $4,194 per Mg of SO_2 for the western United States.[10] Using these values, this assessment estimates that the annual monetized adverse environmental impacts resulting from increases in SO_2 emissions due to this final rule range from $253,000 to $559,000 per Mg ($1990). These results are summarized in Table 10-12.

[8] U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule*.

[9] *Ibid.*

[10] *Ibid.*

Table 10-11

Estimated Annual Human Health and Welfare Benefits from Reductions in VOC Emissions Attributable to the Final Pharmaceutical Industry Effluent Guidelines (1990 dollars)

	Excluding Ozone Mortality (nonattainment areas)	Including Ozone Mortality (all areas)
Dollar Value per Mg	$489	$2,212
VOC Emissions Reductions (Mg)	1,254	3,608
Monetized Benefits (excluding byproduct emissions)	$613,000	$7,980,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

Table 10-12

Estimated Annual Adverse Environmental Impacts from Increases in SO_2 Emissions Attributable to the Final Pharmaceutical Industry Effluent Guidelines (1990 dollars)

	Eastern U.S.		Western U.S.		Total U.S.	
Type of Mortality	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term
Dollar Value per Mg	$4,860	$10,763	$3,516	$4,194	---	---
SO2 Emissions Increases (Mg)	51.8	51.8	0.3	0.3	52.1	52.1
Adverse Monetized Impacts (due to increased emissions)	$252,000	$558,000	$1,100	$1,300	$253,000	$559,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

Total Monetized Benefits

Total monetized air benefits attributable to the Final Pharmaceutical Industry Effluent Guidelines resulting from the reduction of ozone precursors (VOC emissions) from wastewater, after correction for PM and SO_2 increases, range from an adverse environmental impact of $0.2 million ($1990) to a benefit of $7.5 million ($1990). The breakout of these benefits is presented in Table 10-13.

10.4.2.3 Valuation of Benefits from MACT Standards Rule

VOC Analysis

Considering only the wastewater portion of sources covered by the MACT standards rule (at an estimated 23 facilities), EPA estimates that the MACT standards rule will result in reductions in VOC emissions in nonattainment areas alone and in all areas of 2,057 Mg to 16,619 Mg, respectively (Environmental Assessment Report). EPA estimates that the MACT standards rule also will produce benefits due to reductions in fugitive VOC emissions from process vents, storage tanks, and equipment leaks at an estimated 101 facilities in nonattainment and all areas (1,278 Mg and 4,027 Mg, respectively).[11] Considering the wastewater portion only and applying the estimate of the range of the value of a unit reduction of VOC emissions of $489 per Mg to $2,212 per Mg ($1990),[12] EPA estimates that the annual monetized benefits resulting from reductions in VOC emissions (not including adverse impacts of byproduct emissions of PM and SO_2) range from $1.0 million to $36.8 million ($1990). The annual monetized benefits from reductions in all four sources (not including adverse impacts of byproduct emissions) is $1.6 million to $45.7 million ($1990). These results are summarized in Table 10-14.

[11] U.S. EPA, 1997. *Op. cit.*; EPA's Office of Water received pollutant removals for 101 facilities and costs for 98 facilities from OAQPS.

[12] *Ibid.*

Table 10-13

Total Monetized Benefits from Reductions in Ozone Precursors Attributable to the Final Pharmaceutical Industry Effluent Guidelines (1990 dollars)

Pollutant	Monetized Benefits	
	Low	**High**
VOC	$613,000	7,980,000
PM	–$216,000	–$216,000
SO_2	–$559,000	–$253,000
TOTAL	**–$162,000**	**7,510,000**

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

Table 10-14

Estimated Annual Human Health and Welfare Benefits from Reductions in VOC Emissions Attributable to the MACT Standards Rule (1990 dollars)

	Excluding Ozone Mortality (nonattainment areas)	Including Ozone Mortality (all areas)
Dollar Value per Mg	$489	$2,212
VOC Emission Reductions (Mg)		
- Wastewater	2,057	16,619
- Process Vents	936	2,949
- Storage Tanks	33	105
- Equipment Leaks	309	973
Monetized Benefits (excluding byproduct emissions)		
- Wastewater	$1,010,000	$36,800,000
- Process Vents	$458,000	$6,520,000
- Storage Tanks	$16,100	$232,000
- Equipment Leaks	$151,000	$2,150,000
TOTAL Monetized Benefits	**$1,640,000**	**$45,700,000**

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

PM Analysis

EPA estimates that the MACT standards rule will result in an *increase* in PM emissions by 4.2 Mg per year (Environmental Assessment Report). Applying the estimated value of a unit increase in PM emissions of $10,823 per Mg ($1990),[13] EPA estimates that the annual monetized adverse environmental impacts resulting from increases in PM emissions due to the MACT standards rule are $45,500 ($1990).

SO_2 Analysis

EPA estimates that the MACT standards rule will result in an *increase* in SO_2 emissions of 11.0 Mg (10.6 Mg, eastern United States, and 0.4 Mg, western United States) (Environmental Assessment Report). Applying the estimate of the ranges of the value of a unit increase in SO_2 emissions of $4,860 to $10,763 per Mg of SO_2 ($1990) for the eastern United States and $3,516 to $4,194 per Mg of SO_2 ($1990) for the western United States,[14] EPA estimates that the annual monetized adverse environmental impacts resulting from increases in SO_2 emissions due to the MACT standards rule range from $52,900 to $116,000 ($1990). These results are presented in Table 10-15.

Total Monetized Benefits

The total monetized air benefits attributable to the MACT standards rule resulting from reductions of ozone precursors (VOC emissions) from wastewater emission controls, after correction for PM and SO_2 increases, range from $0.8 million ($1990) to $36.7 million ($1990).

In addition, based on the OAQPS analysis of the 101 pharmaceutical manufacturing facilities covered by the MACT standards rule, EPA estimates that the reductions in fugitive VOC emissions from process vents, storage tanks, and equipment leaks would result in a range of monetized air benefits of

[13] U.S. EPA, 1997. *Op. cit*.

[14] *Ibid.*

Table 10-15

Estimated Annual Adverse Environmental Impacts from Increases in SO_2 Emissions Attributable to the MACT Standards Rule (1990 dollars)

	Eastern U.S.		Western U.S.		Total U.S.	
Type of Mortality	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term
Dollar Value per Mg	$4,860	$10,763	$3,516	$4,194	---	---
SO2 Emissions Increases (Mg)	10.6	10.6	0.4	0.4	11.0	11.0
Adverse Monetized Impacts (due to increased emissions)	$51,500	$114,000	$1,400	$1,700	$52,900	$116,000

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

$0.6 million to $8.9 million ($1990).[15] The total monetized benefits from reductions in VOC emissions from all four sources are estimated to be $1.5 million to $45.6 million ($1990). The breakout of these benefits is presented in Table 10-16.

10.4.2.4 Potential Benefits Categories Not Quantified

In addition to acute health effects, ozone is believed to have chronic effects on the human respiratory system. The link between ozone concentration and such chronic health effects in humans, however, is not well understood. Therefore, this category of human health benefits is not considered quantitatively in this analysis. In addition, ozone-induced crop yield changes might have secondary effects due to the responses of the agricultural community to the yield change. For example, crops suffering from the effects of ozone are more susceptible to pestilence and result in an increased use of pesticides. Although the economic implications of these secondary effects of reduced crop yields might be significant, such impacts have not been quantified. Therefore, the resulting benefit estimates will understate the agricultural-related economic benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

10.4.3 Reductions in Cancer Risk

This section describes the assessment of cancer risk reductions expected to result from the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule due to reductions in VOC fugitive air emissions and reductions in pollutant loadings in wastewater discharged to surface waters. Details, including limitations, are available in the Environmental Assessment Report.

10.4.3.1 Reductions in Fugitive Air Emissions Attributable to the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule

Based on the cancer risk assessment for reductions in VOC emissions, EPA estimates that Final Pharmaceutical Industry Effluent Guidelines will result in the avoidance of 0.15 excess cancer cases per year nationwide due to reduced exposure to four identified carcinogens: benzene, chloroform, 1,2-dichloroethane,

[15] U.S. EPA, 1997. *Op. cit*.

Table 10-16

Total Monetized Benefits from Reductions in Ozone Precursors Attributable to the MACT Standards Rule (1990 dollars)

Pollutant	Monetized Benefits	
	Low	**High**
VOC	$1,640,000	$45,700,000
PM	–$45,500	–$45,500
SO_2	–$116,000	–$52,900
TOTAL	**$1,480,000**	**$45,600,000**

Source: Environmental Assessment Report and U.S. EPA, 1997. *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.*

and methylene chloride (Environmental Assessment Report). EPA modeled 74 facility/pollutant release combinations and estimates that 17 facility/pollutant release combinations currently exhibit cancer risk levels exceeding 10^{-6} for a portion of the exposed population. EPA estimates that approximately 1 million people nationwide are exposed to these releases (based on 1990 population data).

The MACT standards rule will result in an additional estimated 0.88 cancer cases avoided per year nationwide via the inhalation exposure route (Environmental Assessment Report). This estimated decrease in cancer risk results from reductions in emissions of three carcinogens: chloroform, 1,2-dichloroethane, and methylene chloride. EPA modeled 43 facility/pollutant release combinations and estimates that 17 facility/pollutant release combinations currently exhibit cancer risk levels exceeding 10^{-6} for a portion of the exposed population. EPA estimates that approximately 4 million people nationwide are exposed to carcinogens as a result of these releases (based on 1990 population data). EPA also estimates that cancer risk will be further reduced due to reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks. However, EPA did not quantify these reductions due to lack of site-specific data.

10.4.3.2 Reductions in Pollutant Loadings to Surface Waters Attributable to the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule

Based on the cancer risk assessment, the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are estimated to result in much less than 0.0001 excess cancer cases avoided per year due to reductions in risk from exposure to contaminants in fish tissue and drinking water (Environmental Assessment Report). This estimate is small because the estimated baseline cancer incidence from consumption of fish tissue and drinking water potentially affected by discharges from pharmaceutical manufacturing facilities at current discharge levels is small.

EPA estimated the cancer risk from consumption of contaminated drinking water and fish tissue by evaluating the risks associated with the effluent from 17 direct dischargers and 113 indirect dischargers for 41 pollutants. EPA estimated the number of excess annual cancer cases avoided due to the final rule to be less than 0.0001 based on fish tissue ingestion. At current discharge levels, total cancer risk to subsistence anglers exceeds 10^{-6} due to the discharge of three carcinogens from three facilities into one stream. Given this risk level and the size of the population exposed, however, estimated cancer incidence is small. Thus, although the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are expected to reduce the risk to acceptable levels (i.e., below 10^{-6}), the magnitude of the human health benefits is negligible.

Total cancer risk for recreational anglers and the general population is not expected to exceed 10^{-6} for any discharges. In the drinking water analysis, EPA estimated no excess annual cancer cases per year at baseline.

10.4.3.3 Valuation Methodology

A monetary value of benefits to society from avoided cancer cases is estimated if fugitive air emissions or wastewater discharges result in excess annual cancer cases with a magnitude significant enough to affect the analysis. The valuation of benefits is based on estimates of society's willingness-to-pay to avoid the risk of premature mortality. A review of willingness-to-pay studies recommends a range of $1.6 to $8.5 million (1986 dollars) for valuing an avoided event of premature mortality or a statistical life saved.[16] Updating this 1986 value to 1990 dollars yields a range of $1.9 to $10.2 million. For this analysis of the Final Pharmaceutical Industry Effluent Guidelines, EPA uses the $1.9 to $10.2 million range for the value of life. A more recent survey of value of life studies by Viscusi also supports this range with the finding that value of life estimates are clustered in the range of $3 to $7 million ($1990).[17]

10.4.3.4 Valuation of Benefits

Based on the cancer risk assessment conducted for fugitive air emissions, EPA estimates that the Final Pharmaceutical Industry Effluent Guidelines will result in 0.15 excess cancer cases avoided per year nationwide (Environmental Assessment Report). This result derives from reduced exposure to four identified carcinogens: benzene, chloroform, 1,2-dichloroethane, and methylene chloride. The estimated monetized value of the human health benefits from these cancer risk reductions ranges from $285,000 to $1.53 million ($1990) annually. In addition, the MACT standards rule will result in 0.88 excess cancer cases avoided per year nationwide. This is due to reduced exposure to three identified carcinogens: chloroform, 1,2-dichloroethane, and methylene chloride. The estimated monetized value of the human health benefits from

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[16] Fisher, Ann, Lauraine G. Chestnut, and Daniel M. Violette, 1989. The Value of Reducing Risk of Death: A Note on New Evidence. *Journal of Policy Analysis and Management.* 8(1): 88-100.

[17] Viscusi, W. Kip, 1992. *Fatal Tradeoffs: Public and Private Responsibilities for Risk*. New York: Oxford University Press.

these cancer risk reductions ranges from $1.7 million to $9.0 million ($1990) annually. Results of these analyses are summarized in Table 10-17.

10.4.4 Environmental Benefits

The Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are expected to generate environmental benefits by improving water quality. These improvements in water quality are expected to result from reduced loadings of toxic substances in the effluent of the regulated facilities. The environmental benefits expected to result from the final rules are discussed below.

10.4.4.1 Description of Benefits

A wide range of environmental benefits is associated with the maintenance and improvement of water quality. These benefits include use values (e.g., recreational fishing), ecological values (e.g., preservation of habitat), and passive use (intrinsic or nonuse) values (e.g., aesthetics). For example, water pollution might affect the quality of the fish and wildlife habitat provided by water resources, thus affecting the species using these resources. This, in turn, might affect the quality and value of recreational experiences of users, such as anglers fishing in the affected streams. EPA considers the value of the recreational fishing benefits and intrinsic benefits resulting from the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule, but does not evaluate the other types of ecological and environmental benefits (e.g., increased assimilative capacity of the receiving stream, protection of terrestrial wildlife and birds that consume aquatic organisms, and improvements to other recreational activities, such as swimming, boating, waterskiing, and wildlife observation) due to data limitations.

EPA evaluates the potential environmental benefits of the final regulations by estimating improvements in the recreational fishing habitats that are affected by pharmaceutical wastewater discharges. EPA first identifies stream segments for which the regulations are expected to eliminate all occurrences of pollutant concentrations in excess of both aquatic life and human health ambient water quality criteria (AWQC) or toxic effect levels (based on stream dilution modeling of 17 direct and 113 indirect dischargers of 41 pollutants to 102 streams). The elimination of pollutant concentrations in excess of AWQC is expected

Table 10-17

Estimated Annual Human Health Benefits from Cancer Risk Reductions (1990 dollars)

	Final Pharmaceutical Industry Effluent Guidelines		MACT Standards Rule	
	Low	**High**	**Low**	**High**
Number of Excess Cancer Cases Avoided	0.15	0.15	0.88	0.88
1990 Value of Life (millions of dollars)	$1.9	$10.2	$1.9	$10.2
TOTAL Monetized Benefits	**$285,000**	**$1,530,000**	**$1,670,000**	**$8,980,000**

Source: Environmental Assessment Report and Fisher, Ann, Lauraine G. Chestnut, and Daniel M. Violette. 1989. The Value of Reducing Risk of Death: A Note on New Evidence. *Journal of Policy Analysis and Management.* 8(1): 88-100.

to result in significant improvements in aquatic habitats. These improvements in aquatic habitats are then expected to improve the quality and value of recreational fishing opportunities. In addition, nonuse (intrinsic) benefits to the general public, as a result of the same improvements in water quality, as described above, are expected. These nonuse benefits (option values, aesthetics, existence values, and bequest values) are based on the premise that individuals who never visit or otherwise use a natural resource might nevertheless be affected by changes in its status or quality.

10.4.4.2 Valuation Methodology

The estimation of the monetary value to society of improved recreational fishing opportunities is based on the concept of a "contaminant-free fishery" as presented by Lyke.[18] Research by Lyke shows that anglers might place a significantly higher value on a contaminant-free fishery than a fishery with some level of contamination. To estimate the increase in value resulting from elimination of pollutant concentrations in excess of AWQC, EPA multiplies the baseline value for benefiting stream segments by the incremental gain in value associated with achievement of the "contaminant-free" condition. Lyke's estimate of the increase in value ranged from 11.1 percent to 31.3 percent. Multiplying by these values yields a range of expected increase in value for the pharmaceutical facility stream segments expected to benefit by elimination of pollutant concentrations in excess of AWQC.

Nonuse benefits are not associated with current use of the affected ecosystem or habitat, but arise rather from: (1) the *realization* of the improvement in the affected ecosystem or habitat resulting from reduced effluent discharges and (2) the value that individuals place on the *potential for use* sometime in the future. Nonuse benefits can be substantial for some resources and are conservatively estimated as one-half of the recreational benefits.[19]

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[18] Lyke, A, 1993. *Discrete Choice Models to Value Changes in Environmental Quality: A Great Lakes Case Study*. Thesis submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy (Agricultural Economics) at the University of Wisconsin-Madison.

[19] Bergstrom, J.C., 1993. *Benefits and Cost Transfer in Natural Resource Planning*. Sixth Interim Report, Athens, GA: University of Georgia, Department of Agricultural and Applied Economics. Bergstrom reviewed a number of sources where use and nonuse values were estimated. Bergstrom estimates the relative magnitude of nonuse value to use value by estimating the ratio of the former to the latter. The 34 ratios estimated by Bergstrom range from 0.1 to 10 with a median ratio of 1.92. The assumption that nonuse values are half of use values therefore should result in conservatively low estimates of nonuse benefits.

10.4.4.3 Valuation of Benefits

To estimate some of the benefits from the improvements in water quality expected to result from the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule, EPA models instream concentration estimates and then compares these estimates to both aquatic life and human health AWQC or toxic effect levels. EPA estimates that modeled end-of-pipe pollutant loadings will decline by 71 percent, from 11.2 million pounds per year under current conditions to 3.3 million pounds per year under the final rules.[20] EPA, in the analysis comparing instream concentration levels to AWQC, estimates that current discharge loadings result in excursions of AWQC at five locations. The analysis also indicates that no excursions are expected to occur at these five sites under the final rules.

EPA estimates that the annual monetized recreational benefits to anglers associated with the expected changes in water quality range from $0.4 million to $1.5 million ($1990) (Environmental Assessment Report). In addition, EPA estimates that the annual monetized intrinsic (nonuse) benefits to the general public, as a result of the same improvements in water quality, range from at least $210,000 to $748,000 ($1990) (Environmental Assessment Report). These intrinsic benefits are estimated as half of the recreational benefits and may be significantly underestimated. Monetized benefits of $232,000 to $828,000 ($1990) of the recreational benefits and $116,000 to $414,000 ($1990) of the intrinsic benefits can be solely attributed to the Final Pharmaceutical Industry Effluent Guidelines. Benefits of both the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are summarized in Table 10-18.

10.4.5 Effects at POTWs

The Final Pharmaceutical Industry Effluent Guidelines contain pretreatment standards for up to 26 pollutants (depending on subcategory) discharged to POTWs by pharmaceutical manufacturing facilities. EPA identified the pollutants to be addressed by pretreatment standards based on analyses of the quantity and concentration of pollutants in the wastewater discharged and the number of facilities that discharge the

[20] These loadings include several pollutants that are not being regulated. Considering only regulated pollutants, EPA expects loadings to decline by 78 percent, from 7.2 million pounds per year under current conditions to 1.6 million pounds per year under the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule.

Table 10-18

Estimated Environmental Benefits (1990 dollars)

	Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule*	
	Low	**High**
Recreational Benefits	$419,000	$1,495,000
Intrinsic (Nonuse) Benefits	$210,000	$748,000
TOTAL Monetized Benefits	**$629,000**	**$2,240,000**

* Includes a portion of recreational and intrinsic monetized benefits ($285,000 to $1,000,000) that cannot be differentiated between Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Source: Environmental Assessment Report.

pollutants. In addition, the MACT standards rule is expected to contribute to the improvement of conditions at POTWs, and these contributions are also discussed here. Although the benefits from reducing adverse effects at POTWs might be substantial, these benefits are not quantified due to data limitations.

10.4.5.1 Description of Benefits

EPA considers three potential sources of benefits to POTWs from the final pretreatment standards: (1) reductions in the likelihood of interference and passthrough; (2) reductions in health risks to POTW workers; and (3) reductions in costs potentially incurred by POTWs in analyzing toxic pollutants and determining whether, and the appropriate level at which, to set local limits. Each of these potential benefit categories is discussed below.

10.4.5.2 Reductions in Interference and Passthrough Problems

As part of the analysis of the effects of pretreatment standards, POTW influent levels are compared to available data on inhibition levels. In the analysis of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule, EPA considers the potential impacts of effluent from 123 facilities discharging 34 pollutants to 94 POTWs. Under current conditions, inhibition problems are projected to occur at three POTWs for three pollutants: acetonitrile, diethylamine, and triethylamine. After the final rules, inhibition problems are projected to remain at the same three POTWs for one of the pollutants: acetonitrile.[21] The benefits cannot be solely attributed to the Final Pharmaceutical Industry Effluent Guidelines. Although the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are not expected to completely eliminate inhibition problems, the reduction in pollutant loadings is expected to reduce the severity of the impact. Sufficient data are not available to monetize these benefits.

[21] These results include pollutants that will not be regulated. Considering only regulated pollutants, EPA projects that under current conditions, inhibition problems will occur at one POTW for two pollutants: diethylamine and triethylamine. After the Final Pharmaceutical Industry Effluent Guidelines and MACT standards rule are promulgated, EPA projects that no inhibition problems caused by regulated pollutants will occur.

Limited evidence is available on the extent to which discharges from pharmaceutical facilities cause POTWs to fail to comply with their permits. There are several documented incidents of large slug loads or accidental releases from pharmaceutical facilities that have negatively affected the environment, including fish kills, degradation of water quality, and odor problems.[22] In addition, many pollutants currently are not controlled in POTW permits because information is lacking on the potential impacts of these pollutants on the environment. Although discharge and failure to treat unregulated pollutants technically do not constitute passthrough, these pollutants enter and potentially have negative effects on the environment.

10.4.5.3 Reductions in Health Risks to POTW Workers

Following procedures outlined in EPA's *Guidance to Protect POTW Workers from Toxic and Reactive Gases and Vapors*,[23] risks to POTW workers from exposure to toxics are evaluated under current conditions and under final pretreatment standards.[24] Occupational exposure levels at POTWs are modeled based on the mixture of vapors that can partition out of influent water into the surrounding air. Risks to POTW workers are evaluated comparing these estimated exposure levels to occupational Threshold Limit Values (TLVs). Toxic substances, particularly the VOCs, in effluent discharges to POTWs pose health risks to POTW workers. EPA evaluates effluent discharged by 131 pharmaceutical facilities to 89 POTWs. Applying the approach described above, EPA expects the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule to reduce occupational risk at 9 of the 14 POTWs where workers are potentially at risk due to exposure to primarily acetonitrile, benzene, chloroform, diethylamine, n-heptane, n-

[22] Note that some of these releases might have been in violation of existing regulations, and thus it might be inappropriate to attribute benefits resulting from proper control of these releases to the final rule. However, if the final rule does reduce the likelihood of such releases, it might be argued that such benefits are attributable to the rule.

[23] U.S. EPA, 1992. *Guidance to Protect POTW Workers from Toxic and Reactive Gases and Vapors*. June. NTIS: PB92-173236/XAB. EPA/812/B-92/001.

[24] The analysis does not consider risks to sewer workers, assuming that these workers would not be exposed to toxic emissions for long periods of time without using protective gear.

hexane, methylene chloride, toluene, and triethylamine.[25] Reductions of occupational risk at five POTWs can be solely attributed to the Final Pharmaceutical Industry Effluent Guidelines. Data are not available to monetize this benefit.

10.4.5.4 Benefits from Reductions in Analytical Costs

Under the National Pretreatment Program, authorized POTWs are required to develop and implement programs to control pollutants discharged by facilities to their systems. Local limits are designed to prevent passthrough and interference, taking into account POTW-specific and effluent-specific characteristics, as well as to implement other specific components of the National Pretreatment Program. In setting local limits, POTWs might need to undertake analyses to determine which pollutants warrant local limits and at what numerical level. Conducting these analyses is expensive—in some cases, on the order of hundreds of thousands of dollars. Thus, establishing pretreatment standards benefits the POTWs by allowing them to avoid the costs of performing these analyses. In addition, it is more efficient to conduct such analyses at the national level, reducing the potential for duplication of effort. Furthermore, categorical pretreatment standards will bolster the legal authority of the local limits POTWs set. POTWs must comply with the requirements contained in effluent guidelines and standards as required in 40 CFR 403. Finally, the standards will allow POTWs to develop technically supportable local limits for nonregulated pollutants that are similar to the pollutants regulated under the pretreatment standards.

10.4.6 Reductions in Systemic Risk

The Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule are expected to generate human health benefits by reducing exposure to toxic substances that cause systemic (noncancer) effects, thus reducing the risks of these associated effects. As in the case of the cancer risk assessment, EPA evaluates systemic hazards from exposure to fugitive air emissions and consumption of contaminated fish tissue and drinking water. Based on this analysis, EPA expects reductions in fugitive air emissions from

[25] These results include impacts of acetonitrile, which will not be regulated. Considering only regulated pollutants, EPA expects the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule will reduce occupational risk at 11 of 13 POTWs where workers are potentially at risk.

wastewater due to the Final Pharmaceutical Industry Effluent Guidelines to result in reduced systemic hazard to 32,300 individuals due to reduced exposure to four identified toxic pollutants: ammonia, chlorobenzene, methyl cellosolve, and triethylamine. EPA estimates that reductions in fugitive air emissions from wastewater due to the MACT standards rule will result in reduced systemic hazard to 370,000 individuals due to reduced exposure to four identified toxic pollutants: ammonia, 4-methyl-2-pentanone, methyl cellosolve, and triethylamine. EPA also expects that reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks will result in reduced systemic hazard. However, these benefits are not quantified due to data limitations. EPA expects that no systemic hazard reductions are expected to result from reduced exposure to contaminated fish tissue or drinking water based on the estimated hazard calculated for each receiving stream under either or both rules.

10.4.7 Other Unquantified Benefits

The above benefit analyses focus mainly on identified compounds with quantifiable toxic or carcinogenic effects. This approach leads to a potentially large underestimation of benefits, since some significant pollutant characterizations are not considered. For example, the analyses do not include the benefits associated with reducing the particulate load (measured as TSS), or the oxygen demand (measured as BOD and COD) of the effluents. TSS loads can degrade ecological habitat by reducing light penetration and primary productivity and through the accumulation of solid particles that alter benthic spawning grounds and feeding habitats. BOD and COD loads can deplete oxygen levels, which can produce mortality or other adverse effects in fish, as well as reduce biological diversity. The benefits analyses are further limited because they concentrate on projected excursions from established minimum standards and do not account for protection of higher quality conditions. Likewise, they do not account for prevention of future impacts that could occur due to increased effluent loadings.

10.4.8 Summary of Results

The estimated annual monetized benefits resulting from the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT standards rule will range from $0.7 million to $11.3 million ($1990). This range includes $285,000 to $1.0 million of the environmental benefits

that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions control portion of the MACT standards rule. The annual monetized benefits resulting solely from the MACT standards rule are estimated to range from $3.2 million to $54.6 million ($1990). Table 10-19 summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of the final rules and in placing a dollar value on these effects. As previously discussed and as indicated in the table, these monetized benefits ranges do not reflect many of the benefit categories expected to result under the final rules, including reduced systemic human health hazards; improved POTW operations/conditions; and improved worker health at POTWs. Therefore, the reported benefit estimate understates the total benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

10.5 COST-BENEFIT COMPARISON

Table 10-20 presents the social costs and benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule. Only the costs and benefits of the selected effluent guidelines options are presented here.

As the table shows, the Final Pharmaceutical Industry Effluent Guidelines are associated with costs totaling $49.6 million, with benefits totaling $0.7 million to $11.3 million ($1990). With costs and benefits of the MACT standards rule included, costs of both rules are $97.0 million ($1990) and benefits of both rules range from $3.9 million to $65.9 million ($1990). The largest benefit category is human health benefits, with about 90 percent of the total dollar value of benefits under the combined rules. Note that the estimate for benefits does not include the dollar value of many important benefits for which monetized estimates could not be developed. Examples of benefit categories not reflected in this estimate including reduced systemic human health hazards; improved POTW operations/conditions; and improved worker health at POTWs. Therefore, the reported benefit estimate understates the total benefits of the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Table 10-19

Potential Annual Economic Benefits from the Final Pharmaceutical Industry Effluent Guidelines and the MACT Standards Rule (millions of 1990 dollars)

Benefits Category	Estimated Economic Benefit			
	Pharmaceutical Industry Guidelines		MACT Rule	
	Low	High	Low	High
Reduced Emissions of Ozone Precursors	-$0.162	$7.51	$1.48	$45.6
Reduced Cancer Risk	$0.285	$1.53	$1.67	$8.98
Improved Environmental Conditions	$0.629	$2.24	Unquantified	Unquantified
Improved POTW Operations (Inhibition and Sludge Contamination), Occupational Conditions	Unquantified	Unquantified	Unquantified	Unquantified
Reduced Systemic Risk	Unquantified	Unknown	Unquantified	Unquantified
TOTAL Monetized Benefits	**$0.752**	**$11.3**	**$3.15**	**$54.6**

Note: The Final Pharmaceutical Industry Effluent Guidelines benefits include a portion of environmental monetized benefits that cannot be solely attributed to the effluent guidelines alone ($285,000 to $1 million, 1990 dollars). Specifically, two facilities included in the modeling were required to have MACT strippers and were also costed for additional strippers to meet the Final Pharmaceutical Industry Effluent Guidelines. Overall removals due to these strippers cannot be differentiated between the MACT standards rule and the Final Pharmaceutical Industry Effluent Guidelines requirements.

The benefit values attributable for the MACT standards rule associated with reduced ozone precursor emissions from the wastewater emissions control portion of the MACT standards rule include adverse impacts related to increased energy consumption. Adverse impacts due to increased energy consumption from control of the other sources are not quantified due to data limitations.

Table 10-20

Total Costs and Benefits of the Final Pharmaceutical Industry Effluent Guidelines and MACT Standards Rule
(thousands of 1990 dollars)

Type of Benefit	Total Social Cost or Benefit Effluent Guidelines	Total Social Cost or Benefit MACT Standards Rule	Total Social Cost or Benefit Effluent Guidelines + MACT Standards Rule
Compliance Costs	$49,362	$47,447	$96,809
Administrative Costs	$207	unquantified *	$207
Unemployment Administrative Costs	$11	$10	$21
Total Social Costs	$49,580	$47,457	$97,037
Human Health Benefits **	$123 - $9,040	$3,150 - $54,600	$3,273 - $63,640
Recreational Benefits	$419 - $1,495	unquantified	$419 - $1,495
Nonuse Benefits	$210 - $748	unquantified	$210 - $748
POTW Benefits +	unquantified	unquantified	unquantified
Total Benefits ++	**$752 - $11,300**	**$3,150 - $54,600**	**$3,902 - $65,900**

* Administrative costs were not calculated for the MACT standards rule but are expected to be small relative to the total costs of the two rules combined.
** Includes ozone reductions and cancer reductions.
+ Data are not available to monetize this benefit.
++ This range includes $285,000 to $1.0 million ($1990) ($340,000 to $1.2 million, $1997) of the environmental benefits that cannot be differentiated between the Final Pharmaceutical Industry Effluent Guidelines and the wastewater emissions portion of the MACT standards rule. The total benefits numbers differ slightly from those presented in the preamble due to rounding of the benefits to two significant digits in the preamble.

Source: Table 10-6 and 10-19 of this EA.

APPENDIX A

ADDITIONAL DISCUSSION OF ASSUMPTIONS USED OR CONSIDERED FOR USE IN THE COST ANNUALIZATION MODEL

A.1 FINANCIAL ASSUMPTIONS

The cost annualization model incorporates several financial assumptions:

- Depreciation method
- Timing between initial investment and operation
- Depreciable lifetime for equipment
- Tax shields on interest payments
- Discount rates

Each assumption, and the alternatives examined in making the assumption, is discussed in detail below.

A.1.1 Depreciation Method

The Agency examined four alternatives for depreciating capital investments:

- Modified Accelerated Cost Recovery System (MACRS)
- Straight-line depreciation
- Section 169 of the Internal Revenue Code
- Section 179 of the Internal Revenue Code

Modified Accelerated Cost Recovery System (MACRS) applies to assets put into service after December 31, 1986. MACRS involves the ability to write off greater portions of the investment in the early

years. In contrast, the straight-line depreciation writes off a constant amount of the investment each year. MACRS offers companies an advantage over the straight-line method because a company's income can be reduced under MACRS by a greater amount in the early years when the time value of money is greater. Table A-1 illustrates the effects of the difference in timing in writing off a $100,000 capital investment. The absolute amount depreciated over the 16-year period is the same—$100,000 for both depreciation methods. The sum of the tax shields is also the same for both methods—$100,000 x 38.46 percent or $38,460. The difference in timing, however, means that MACRS provides a $1,429 benefit over straight-line depreciation (i.e., the difference between the present values of the tax shields). The benefit of using MACRS is clear; MACRS is the depreciation used in the cost annualization model.

Section 169 of the Internal Revenue Code provides an option to amortize pollution control facilities over a 5-year period.[1] Under this provision, 75 percent of the investment could be rapidly amortized in a 5-year period using a straight line method. The 75 percent figure is based on the ratio of allowable lifetime (15 years) to the estimated usable lifetime (20 years) as specified in the Internal Revenue Code Section 169, Subsection (f). Although the tax provision enables the facility to expense the investment over a shorter time period, the advantage is substantially reduced because only 75 percent of the capital investment can be recovered. Tables A-2 and A-3 illustrate the differences between using MACRS and the Section 169 tax provision using hypothetical costs. The present value of the tax shield from depreciation (Column 4) decreases slightly, from $24,790 (Table A-2) to $23,651 (Table A-3). Because there may be no benefit associated with the provision, and the facilities might not get the required certification to take advantage of it, the provision was not included in the cost annualization model.

The Agency also considered the Internal Revenue Code Section 179 provision to elect to expense up to $17,500 the year the investment is placed into service.[2] The Agency assumes that this provision is applied to other investments for the business entity. Its absence in the cost annualization model may result in a slightly more conservative (i.e., higher) estimate of the after-tax annualized cost for the facility.

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[1] Research Institute of America, Inc., 1995. *The Complete Internal Revenue Code*. New York, NY: Research Institute of America, Inc. January.

[2] This assumes that the investment costs do not exceed $200,000 (*The Complete Internal Revenue Code*, Section 179(b)(2); *ibid.*).

Table A-1

Depreciation Methods
Comparison of Straight Line vs. Modified Accelerated Cost Recovery System (MACRS)

Inputs:		
Capital Cost ($):		$100,000
Discount Rate :		7.0%
Depreciable Lifetime (yrs):		15
Marignal Tax Rates:		
	Federal	34.00%
	State	6.75%
	Overall	38.46%

	Straight-Line			MACRS		
Year	Depreciation Rate	Depreciation For Year	Tax-Shield	Depreciation Rate	Depreciation For Year	Tax-Shield
1	0.000%	$0	$0	0.000%	$0	$0
2	6.670%	$6,670	$2,565	10.000%	$10,000	$3,846
3	6.670%	$6,670	$2,565	9.643%	$9,643	$3,708
4	6.670%	$6,670	$2,565	9.272%	$9,272	$3,566
5	6.670%	$6,670	$2,565	8.886%	$8,886	$3,417
6	6.670%	$6,670	$2,565	5.655%	$5,655	$2,174
7	6.670%	$6,670	$2,565	5.655%	$5,655	$2,175
8	6.660%	$6,660	$2,565	5.655%	$5,655	$2,175
9	6.670%	$6,670	$2,565	5.655%	$5,655	$2,175
10	6.660%	$6,660	$2,565	5.655%	$5,655	$2,175
11	6.670%	$6,670	$2,565	5.655%	$5,655	$2,175
12	6.660%	$6,660	$2,565	5.655%	$5,655	$2,175
13	6.670%	$6,670	$2,565	5.655%	$5,655	$2,175
14	6.660%	$6,660	$2,565	5.655%	$5,655	$2,175
15	6.670%	$6,670	$2,565	5.655%	$5,655	$2,175
16	6.670%	$6,670	$2,565	5.655%	$5,655	$2,175
Sum	100.00%	$100,000	$38,474	100.00%	$100,000	$38,457
Present Value		$60,729	$23,361		$64,466	$24,790
Net Benefit of Using MACRS over Straight-Line Method (Year 1 dollars)						$1,429

Source: See text.

Table A-2

Spreadsheet for Annualizing Costs

INPUTS

Facility Code:	30387
Facility Type:	AC/Direct
Option Number:	BAT/Opt. 1
Initial Capital Cost ($):	$100,000
Annual Operation & Maintenance Cost ($):	$10,000
Equipment Lifetime	15
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined	38.46%

Column 1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year	Tax Shield From Depreciation	O&M Cost	O&M Tax Shield	Cash Outflow	Cash Outflow After Tax Shields
1	0.000%	$0	$0	$0	$0	$100,000	$100,000
2	10.000%	$10,000	$3,846	$10,000	$3,846	$10,000	$2,309
3	9.643%	$9,643	$3,708	$10,000	$3,846	$10,000	$2,446
4	9.272%	$9,272	$3,566	$10,000	$3,846	$10,000	$2,589
5	8.886%	$8,886	$3,417	$10,000	$3,846	$10,000	$2,738
6	5.655%	$5,655	$2,174	$10,000	$3,846	$10,000	$3,980
7	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
8	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
9	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
10	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
11	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
12	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
13	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
14	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
15	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
16	5.655%	$5,655	$2,175	$10,000	$3,846	$10,000	$3,980
Sum	100.00%	$100,005	$38,457	$150,000	$57,683	$250,000	$153,861
Present Value		$64,466	$24,790	$91,079	$35,024	$191,079	$131,264

	After Tax Shield	Before Tax Shield
Present Value of Incremental Costs:	$131,264	$191,079
Annualized Cost:	$13,895	$20,227

Notes: This spreadsheet assumes that a modified accelerated cost recovery system (MACRS) is used to depreciate capital expenditures.

Table A-3

Spreadsheet for Annualizing Costs Using Section 169 Provision

INPUTS

Facility Type:	30387
Facility Code:	AC/Direct
Option Number:	BAT/Opt. 1
Initial Capital Cost ($):	$100,000
Annual Operation & Maintenance Cost ($):	$10,000
Equipment Lifetime:	15
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined	38.46%

Column 1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year	Tax Shield From Depreciation	O&M Cost	O&M Tax Shield	Cash Outflow	Cash Outflow After Tax Shields
1	0.00%	$0	$0	$0	$0	$100,000	$100,000
2	20.00%	$15,000	$5,768	$10,000	$3,846	$10,000	$386
3	20.00%	$15,000	$5,768	$10,000	$3,846	$10,000	$386
4	20.00%	$15,000	$5,768	$10,000	$3,846	$10,000	$386
5	20.00%	$15,000	$5,768	$10,000	$3,846	$10,000	$386
6	20.00%	$15,000	$5,768	$10,000	$3,846	$10,000	$386
7	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
8	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
9	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
10	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
11	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
12	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
13	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
14	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
15	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
16	0.00%	$0	$0	$10,000	$3,846	$10,000	$6,154
Sum	100.00%	$75,000	$28,840	$150,000	$57,690	$250,000	$163,470
Present Value		$61,503	$23,650	$91,079	$35,029	$191,079	$132,400

	After Tax Shield	Before Tax Shield
Present Value of Incremental Costs:	$132,400	$191,079
Annualized Cost:	$14,016	$20,227

A.1.2 Timing Between Initial Investment and Operation

A business cannot begin to depreciate a capital investment before it goes into operation. Although the midyear convention is frequently used when calculating depreciation, it is not appropriate for the analysis in Section Four. Approximately one year would be required to build and install most of the equipment considered in the regulatory alternatives. Additional time might be required for design, permitting, and site preparation. The cost annualization model, therefore, assumes a 1-year delay from the capital expenditure to the beginning of operation. As shown in Table A-2, the capital expenditure is listed in Year 1, but depreciation and annual O&M costs are not listed until Year 2 (assumed to be the first full year of operation). The 1-year delay also changes each year's depreciation rates (see column 2).

A.1.3 Depreciable Lifetime for the Equipment

Tables A-4 through A-8 present an analysis of the sensitivity of annualized cost estimates to changes in depreciation methods and project lifetime. The annualized cost model specifies 20 to 25-year service lifetimes for wastewater treatment technology. According to the IRS tax code, capital equipment with that service life should be depreciated over 15 years. Fifteen years is also the EPA standard project life used for analysis of impacts for effluent guidelines. The tables test the effects of changes in depreciation methods and schedules on estimates of annualized costs; significant changes in annualized cost estimates could cause significant changes in cost effectiveness calculations and impact estimates.

Table A-4 presents estimates of pre- and posttax annualized compliance costs and the present value of total pre- and posttax costs over the project lifetime for the pharmaceuticals industry for the selected options. The standard estimates use the 15-year accelerated depreciation and 15-year project life, which are the current assumptions in the pharmaceutical analyses to date. The figures shown in Table A-5 for a hypothetical facility therefore match the way in which costs were calculated for the current impact analyses. Variation 1 uses a 15-year straight-line depreciation and 15-year project life. The only difference between the standard version and Variation 1 occurs in posttax cost estimates because the change in the depreciation method only changes the size and timing of the tax shield. Posttax annualized costs under Variation 1 exceed standard cost estimates by less than one percent. The present value of posttax costs for Variation 1 exceeds

Table A-4

Sensitivity Analysis of Annualized Cost Estimation to Depreciation and Project Life for All Affected Pharmaceutical Facilities

Cost	Standard	Variation 1	Variation 2	Variation 3
		BAT-A/C		
Capital	$3,532,000	$3,532,000	$3,532,000	$3,532,000
O&M	$2,165,000	$2,165,000	$2,165,000	$2,165,000
Annualized, post-tax	$1,565,871	$1,571,254	$1,547,865	$1,618,954
Annualized, pre-tax	$2,461,257	$2,461,257	$2,461,257	$2,545,478
Present Value, post-tax	$14,792,237	$14,843,082	$14,622,135	$9,667,256
Present Value, pre-tax	$23,250,634	$23,250,634	$23,250,634	$15,199,812
		BAT-B/D		
Capital	$0	$0	$0	$0
O&M	$0	$0	$0	$0
Annualized, post-tax	$0	$0	$0	$0
Annualized, pre-tax	$0	$0	$0	$0
Present Value, post-tax	$0	$0	$0	$0
Present Value, pre-tax	$0	$0	$0	$0
		BPT-A/C		
Capital	$2,879,000	$2,879,000	$2,879,000	$2,879,000
O&M	$2,293,000	$2,293,000	$2,293,000	$2,293,000
Annualized, post-tax	$1,589,836	$1,594,223	$1,575,158	$1,613,073
Annualized, pre-tax	$2,515,543	$2,515,543	$2,515,543	$2,551,646
Present Value, post-tax	$15,018,617	$15,060,063	$14,879,964	$9,632,141
Present Value, pre-tax	$23,763,447	$23,763,447	$23,763,447	$15,236,641
		BPT-B/D		
Capital	$3,840,000	$3,840,000	$3,840,000	$3,840,000
O&M	$1,400,000	$1,400,000	$1,400,000	$1,400,000
Annualized, post-tax	$1,136,456	$1,142,308	$1,116,879	$1,230,333
Annualized, pre-tax	$1,756,293	$1,756,293	$1,756,293	$1,906,621
Present Value, post-tax	$10,735,701	$10,790,980	$10,550,766	$7,346,687
Present Value, pre-tax	$16,591,080	$16,591,080	$16,591,080	$11,385,005
		PSES-A/C		
Capital	$88,237,000	$88,237,000	$88,237,000	$88,237,000
O&M	$31,564,000	$31,564,000	$31,564,000	$31,564,000
Annualized, post-tax	$25,754,491	$25,888,954	$25,304,647	$27,934,605
Annualized, pre-tax	$39,772,750	$39,772,750	$39,772,750	$43,264,381
Present Value, post-tax	$243,293,623	$244,563,853	$239,044,105	$166,805,866
Present Value, pre-tax	$375,719,198	$375,719,198	$375,719,198	$258,344,531
		PSES-B/D		
Capital	$7,789,000	$7,789,000	$7,789,000	$7,789,000
O&M	$5,885,000	$5,885,000	$5,885,000	$5,885,000
Annualized, post-tax	$4,112,172	$4,124,041	$4,072,462	$4,187,121
Annualized, pre-tax	$6,498,503	$6,498,503	$6,498,503	$6,615,809
Present Value, post-tax	$38,846,242	$38,958,370	$38,471,122	$25,002,549
Present Value, pre-tax	$61,389,074	$61,389,074	$61,389,074	$39,504,968

Standard: 15-year accelerated depreciation, 15-year project lifetime
Variation 1: 15-year straight-line depreciation, 15-year project lifetime
Variation 2: 7-year straight-line depreciation, 15-year project lifetime
Variation 3: 7-year straight-line depreciation, 7-year project lifetime

Table A-5

Sample Spreadsheet for Annualizing Costs
Standard: 15-Year Accelerated Depreciation, 15-Year Project Lifetime

INPUTS	
Facility Code:	30387
	$1990
Initial Capital Cost ($):	$3,532,000
Annual Operation & Maintenance Cost ($):	$2,165,000
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined	38.46%

Column 1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year	Tax Shield From Depreciation	O&M Cost	O&M Tax Shield	Cash Outflow	Cash Outflow After Tax Shields
1	0.000%	$0	$0	$0	$0	$3,532,000	$3,532,000
2	10.000%	$353,200	$135,823	$2,165,000	$832,551	$2,165,000	$1,196,626
3	9.643%	$340,586	$130,972	$2,165,000	$832,551	$2,165,000	$1,201,477
4	9.272%	$327,486	$125,935	$2,165,000	$832,551	$2,165,000	$1,206,514
5	8.886%	$313,841	$120,688	$2,165,000	$832,551	$2,165,000	$1,211,762
6	5.655%	$199,717	$76,801	$2,165,000	$832,551	$2,165,000	$1,255,648
7	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
8	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
9	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
10	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
11	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
12	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
13	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
14	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
15	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
16	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641
Sum	100.00%	$3,532,176	$1,358,298	$32,475,000	$12,488,261	$36,007,000	$22,160,440
Present Value		$2,276,938	$875,597	$19,718,634	$7,582,801	$23,250,634	$14,792,237

	After Tax Shield	Before Tax Shield
Present Value of Incremental Costs:	$14,792,237	$23,250,634
Annualized Cost:	$1,565,871	$2,461,257

Table A-6

Sample Spreadsheet for Annualizing Costs
Variation 1: 15-Year Straight-line Depreciation, 15-Year Project Lifetime

INPUTS

Facility Code:	30387
	$1990
Initial Capital Cost ($):	$3,532,000
Annual Operation & Maintenance Cost ($):	$2,165,000
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined	38.46%

Column 1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year	Tax Shield From Depreciation	O&M Cost	O&M Tax Shield	Cash Outflow	Cash Outflow After Tax Shields
1	0.00%	$0	$0	$0	$0	$3,532,000	$3,532,000
2	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
3	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
4	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
5	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
6	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
7	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
8	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
9	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
10	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
11	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
12	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
13	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
14	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
15	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
16	6.67%	$235,478	$90,553	$2,165,000	$832,551	$2,165,000	$1,241,896
Sum	100.00%	$100,000	$1,358,299	$32,475,000	$12,488,261	$36,007,000	$22,160,440
Present Value		$2,144,717	$824,751	$19,718,634	$7,582,801	$23,250,634	$14,843,082

	After Tax Shield	Before Tax Shield
Present Value of Incremental Costs:	$14,843,082	$23,250,634
Annualized Cost:	$1,571,254	$2,461,257

Table A-7

Sample Spreadsheet for Annualizing Costs
Variation 2: 7-Year Straight-line Depreciation, 15-Year Project Lifetime

INPUTS

Survey ID #:	30387
	$1990
Initial Capital Cost ($):	$3,532,000
Annual Operation & Maintenance Cost ($):	$2,165,000
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined	38.46%

Column 1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year	Tax Shield From Depreciation	O&M Cost	O&M Tax Shield	Cash Outflow	Cash Outflow After Tax Shields
1	0.00%	$0	$0	$0	$0	$3,532,000	$3,532,000
2	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
3	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
4	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
5	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
6	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
7	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
8	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
9		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
10		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
11		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
12		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
13		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
14		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
15		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
16		$0	$0	$2,165,000	$832,551	$2,165,000	$1,332,449
Sum	100.00%	$3,531,996	$1,358,229	$32,475,000	$12,488,261	$36,007,000	$22,160,510
Present Value		$2,719,279	$1,045,699	$19,718,634	$7,582,801	$23,250,634	$14,622,135

	After Tax Shield	Before Tax Shield
Present Value of Incremental Costs:	$14,622,135	$23,250,634
Annualized Cost:	$1,547,865	$2,461,257

Table A-8

Sample Spreadsheet for Annualizing Costs
Variation 3: 7-Year Straight-line Depreciation, 7-Year Project Lifetime

INPUTS

Survey ID #:	30387
	$1990
Initial Capital Cost ($):	$3,532,000
Annual Operation & Maintenance Cost ($):	$2,165,000
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined	38.46%

Column 1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year	Tax Shield From Depreciation	O&M Cost	O&M Tax Shield	Cash Outflow	Cash Outflow After Tax Shields
1	0.00%	$0	$0	$0	$0	$3,532,000	$3,532,000
2	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
3	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
4	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
5	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
6	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
7	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
8	14.29%	$504,571	$194,033	$2,165,000	$832,551	$2,165,000	$1,138,417
9		$0	$0	$0	$0	$0	$0
10		$0	$0	$0	$0	$0	$0
11		$0	$0	$0	$0	$0	$0
12		$0	$0	$0	$0	$0	$0
13		$0	$0	$0	$0	$0	$0
14		$0	$0	$0	$0	$0	$0
15		$0	$0	$0	$0	$0	$0
16		$0	$0	$0	$0	$0	$0
Sum	100.00%	$3,531,996	$1,358,229	$15,155,000	$5,827,855	$18,687,000	$11,500,916
Present Value		$2,719,279	$1,045,699	$11,667,812	$4,486,857	$15,199,812	$9,667,256

	After Tax Shield	Before Tax Shield
Present Value of Incremental Costs:	$9,667,256	$15,199,812
Annualized Cost:	$1,618,954	$2,545,478

those of the standard estimate by a similar percentage. Variation 2 uses a 7-year straight-line depreciation method and a 15-year project life. This results in slightly smaller estimates of posttax annualized costs and the present value of posttax costs than using Variation 1 or the standard analysis. Variation 3 presents estimates using 7-year straight-line depreciation and a 7-year project life. The present value of costs is smaller under Variation 3 than the other methods, however, annualized cost estimates are higher.

Tables A-5 through A-8 provide an illustration of why these results occur. These exhibits present a sample cost annualization spreadsheet calculation for a fictitious facility under the four variations described above. The same data is used in each calculation; the only difference between exhibits is the depreciation method and project life. The fictitious facility has capital costs of $3,532,000 and annual operating and maintenance (O&M) costs of $2,165,000. Table A-5 presents the standard calculation.[3] When compared with Variation 1 (Table A-6), the accelerated depreciation (Table A-5) provides larger tax shields to the facility in the early years of the project, when the present value of a dollar is greater, than in later years. Thus the present value of the tax shield from depreciation is larger under the standard method than under Variation 1, and the present value of posttax costs and posttax annualized costs are both smaller. The depreciation and tax shield from depreciation (columns 3 and 4 of the sample spreadsheet) are the only differences between the two versions. A 7-year depreciation period with a 15-year project life (Variation 2, Table A-7) produces essentially the same results. The 7-year depreciation period, although using the straight-line method, moves more of the depreciation and tax shield from depreciation into the early years, when the present value of a dollar is greater than in later years. Finally, the present value of costs under Variation 3 (Table A-8) is smaller than the other options because only seven years of O&M costs are included. However, the annualized costs under Variation 3 (Table A-8) are greater because the stream of costs was annualized over 8 years instead of 16. Thus annualized costs under Variation 3 are slightly larger than those calculated assuming longer project lives.

It is clear that changes in the project life have a much larger impact on annualized cost estimates than changes in the method of depreciation. In fact, if the pharmaceuticals industry depreciates its capital costs over 7 years instead of 15, posttax annualized compliance costs will be smaller than those estimated by the current cost annualization methodology. Changing the period of depreciation does not imply changing the

[3] Note that the methodology assumes the wastewater treatment technology takes one year to purchase and install. The cost annualization model charges all capital costs to the first year.

project lifetime, therefore the 7-year depreciation period is compatible with the 15-year project analysis period. Only if the equipment truly has a life less than 15 years will the annualized costs be substantially greater. It is highly unlikely that pollution control equipment will need to be replaced in less than 15 years, otherwise IRS would have difficulty mandating a 15-year depreciable life on this type of equipment. IRS sets the 15-year depreciable life because the actual expected life is generally greater, i.e., 20 to 25 years.

A.1.4 Tax Shields on Interest Payments

The cost annualization model does not consider tax shields on interest paid to finance new pollution control equipment. A facility could finance the investment through a bank loan (debt), money from working capital, issuance of a corporate bond, or selling additional stock (equity shares). In any case, the cost annualization model assumes a cost to the facility to use the money (the discount/interest rate), whether the money is paid as interest or is the opportunity cost of internal funding. According to current tax law, if a facility finances the investment using debt, the associated interest expenses can be deducted, thereby reducing taxable income.[4] The tax shield on the interest payments, therefore, would reduce the after-tax annualized cost. It is not known what mix of debt and capital a facility will use to finance the cost of pollution control equipment. According to Table A-9, which illustrates the effects of 100-percent debt financing, the after-tax annualized cost would drop by approximately 3 percent due to tax shields on the interest payments. If the facility financed the entire investment out of working capital, there would be no associated tax benefit and the after-tax cost should be calculated without interest tax shields. To maintain a conservative estimate of the after-tax annualized cost, tax shields on interest payments are not included in the cost annualization model.

A.1.5 Discount Rates

A company can use internal financing, external financing, or some combination to raise the capital for upgrading its wastewater treatment system. Retained earnings and working capital are examples of internal funding sources. Debt and external equity (stock issuance) are examples of external funding sources.

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[4] CCH, 1994, *State Tax Handbook*. Chicago, IL: CCH.

Table A-9

Spreadsheet for Annualizing Costs with Interest Payments

INPUTS

Facility Type:	30387
Facility Code:	AC/Direct
Option Number:	BAT/Opt. 1
Initial Capital Cost ($):	$3,532,000
Annual Operation & Maintenance Cost ($):	$2,165,000
Real Discount Rate:	7.0%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined	38.46%

Column 1	2	3	4	5	6	7	8	9	10
Year	Depreciation Rate	Depreciation For Year	Tax Shield From Depreciation	O&M Cost	O&M Tax Shield	Cash Outflow	Cash Outflow After Tax Shields	Interest Payments	Interest Payment Tax Shield
1	0.000%	$0	$0	$0	$0	$3,532,000	$3,532,000	$0	$0
2	10.000%	$353,200	$135,823	$2,165,000	$832,551	$2,165,000	$1,196,626	$0	$0
3	9.643%	$340,586	$130,972	$2,165,000	$832,551	$2,165,000	$1,201,477	$0	$0
4	9.272%	$327,486	$125,935	$2,165,000	$832,551	$2,165,000	$1,206,514	$0	$0
5	8.886%	$313,841	$120,688	$2,165,000	$832,551	$2,165,000	$1,211,762	$0	$0
6	5.655%	$199,717	$76,801	$2,165,000	$832,551	$2,165,000	$1,255,648	$0	$0
7	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
8	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
9	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
10	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
11	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
12	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
13	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
14	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
15	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
16	5.655%	$199,735	$76,808	$2,165,000	$832,551	$2,165,000	$1,255,641	$0	$0
Sum	100.00%	$3,532,176	$1,358,298	$32,475,000	$12,488,261	$36,007,000	$22,160,440	$0	$0
Present Value		$861,621	$331,336	$6,288,687	$2,418,315	$9,820,687	$7,071,036	$0	$0

	After Tax Shield	Before Tax Shield
Present Value of Incremental Costs:	$7,071,036	$9,820,687
Annualized Cost:	$2,426,608	$3,370,221
Annualized Interest Tax Shield:	$0	
Annualized Cost After Interest Tax Shield:	$2,426,608	

Notes: This spreadsheet assumes that a modified accelerated cost recovery system (MACRS) is used to depreciate capital expenditures.

The respondents supplied their discount rate (defined as the weighted average marginal cost of capital given their mix of debt and equity) in the Section 308 Survey.

The Agency does not use the discount rate provided by the facility, but assumes a discount rate of 7 percent in the cost annualization model based on a social discount rate provided in OMB Guidance.[5]

A.2 AVERAGE STATE TAX RATE

Table A-10 lists each state's top corporate and individual tax rates and calculates national average state tax rates.[6] The cost annualization model uses the average state tax rate because of the complexities in the industry; for example, a facility could be located in one state, while its corporate headquarters are located in a second state. Given the uncertainty over which state tax rate applies to a given facility's revenues the average state tax rate is used in the cost annualization model for all facilities. The average rate over all states is 6.75 percent.

A.3 COST ANNUALIZATION MODEL AND TOTAL COST ASSESSMENT

The Total Cost Assessment (TCA) approach for evaluating pollution prevention alternatives is a comprehensive financial analysis of the life-cycle costs and savings of a pollution prevention project.[7] A TCA approach includes:

- Internal allocation of environmental costs to product lines or processes through full cost accounting.

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[5] OMB, 1996. *Economic Assessment of Federal Regulations Under Executive Order No. 12866.* January 11.

[6] CCH, 1994. *Op. cit.*

[7] U.S. EPA, 1992. *Total Cost Assessment: Accelerating Industrial Pollution Prevention Through Innovative Project Financial Analysis*. Washington, D.C.: U.S. EPA, Office of Pollution Prevention and Toxics.

Table A-10

State Income Tax Rates

State	Corporate Income Tax Rate	Basis for States with Graduated Tax Tables	Personal Income Tax Upper Rate	Basis for States with Graduated Tax Tables
Alabama	5.00%		5.00%	$3,000+
Alaska	9.40%	$90,000+	0.00%	
Arizona	9.00%		6.90%	$150,000+
Arkansas	6.50%	$100,000+	7.00%	$25,000+
California	9.30%		11.00%	$215,000+
Colorado	5.00%		5.00%	
Connecticut	11.50%		4.50%	
Delaware	8.70%		7.70%	$40,000+
Florida	5.50%		0.00%	
Georgia	6.00%		6.00%	$7,000+
Hawaii	6.40%	$100,000+	10.00%	$21,000+
Idaho	8.00%		8.20%	$20,000+
Illinois	4.80%		3.00%	
Indiana	3.40%		3.40%	
Iowa	12.00%	$250,000+	9.98%	$47,000+
Kansas	4.00%	$50,000+	7.75%	$30,000+
Kentucky	8.25%	$250,000+	6.00%	$8,000+
Louisiana	8.00%	$200,000+	6.00%	$50,000+
Maine	8.93%	$250,000+	8.50%	$33,000+
Maryland	7.00%		6.00%	$100,000+
Massachusetts	9.50%		5.95%	
Michigan	2.30%		4.40%	
Minnesota	9.80%		8.50%	$50,000+
Mississippi	5.00%	$10,000+	5.00%	$10,000+
Missouri	6.25%		6.00%	$9,000+
Montana	6.75%		11.00%	$63,000+
Nebraska	7.81%	$50,000+	6.99%	$27,000+
Nevada	0.00%		0.00%	
New Hampshire	7.00%		0.00%	
New Jersey	7.25%		6.65%	$75,000+
New Mexico	7.60%	$1Million+	8.50%	$42,000+
New York	9.00%		7.88%	$13,000+
North Carolina	7.75%		7.75%	$60,000+
North Dakota	10.50%	$50,000+	12.00%	$50,000+
Ohio	8.90%	Based on Stock Value	7.50%	$200,000+
Oklahoma	6.00%		7.00%	$10,000+
Oregon	6.60%		9.00%	$5,000+
Pennsylvania	9.90%	1997 and thereafter	2.80%	
Rhode Island *	9.00%		10.40%	$250,000+
South Carolina	5.00%		7.00%	$11,000+
South Dakota	0.00%		0.00%	
Tennesee	6.00%		0.00%	
Texas	0.00%		0.00%	
Utah	5.00%		7.20%	$4,000+
Vermont *	8.25%	$250,000+	9.45%	$250,000+
Virginia	6.00%		5.75%	$17,000+
Washington	0.00%		0.00%	
West Virginia	9.00%		6.50%	$60,000+
Wisconsin	7.90%		6.93%	$20,000+
Wyoming	0.00%		0.00%	
Average:	6.61%		5.84%	

Notes: Basis for rates is reported to nearest $1,000.
Personal income tax rates for Rhode Island and Vermont based on federal tax (not taxable income).
Tax rates given here are equivalents for highest personal federal tax rate.

Source: CCH, Inc., 1994. State Tax Handbook. Chicago, IL: CCH.
Personal communication, Maureen Kaplan, ERG, and Commerce Clearinghouse (CCH) Inc., to resolve discrepancies on tax rate for Missouri and Rhode Island, March 30, 1995.

- Financial analysis of direct and indirect costs, short- and long-term costs, liability costs, and less tangible benefits of an investment.
- Evaluation of project costs and savings over a long-time horizon, e.g., 10 to 15 years.
- Measures of profitability that capture the long-term profitability of the project, e.g., net present value and internal rate of return.

TCA approaches are being developed as alternatives to traditional financial analysis methods to capture and properly evaluate the long-term costs and savings inherent in pollution prevention activities.

The cost annualization model incorporates several features of a total cost assessment analysis, including:

- Long-time horizon (the annualization model uses a 15-year time frame).
- Short- and long-term costs.
- Depreciation, taxes, inflation, and discount rate.
- The associated closure analysis (Section Five), which uses the net present value of the investment calculated in the cost annualization model to evaluate the long-term impacts on profitability.

The economic analysis differs from the TCA approach in that it does not include a "liability avoided" component or an evaluation of the less tangible benefits of the regulation. There are insufficient data to estimate potential future liability costs for each facility. The exclusion of this parameter results in a more conservative analysis where potential impacts are not offset by avoiding future liability costs. A separate analysis and report compare the costs and benefits of the regulation.

APPENDIX B

MACT CAPITAL AND OPERATING AND MAINTENANCE COSTS

Table B-1 presents the MACT standards costs that the Office of Water (OW) received from the Office of Air Quality Planning and Standards (OAQPS) for the facilities in the Final Pharmaceutical Industry Effluent Guidelines analysis. The costs, which were originally in 1995 dollars, were deflated to 1990 dollars for use in the cost annualization model (see Section Four) to calculate the baselines discussed in Sections Five and Six. The MACT capital cost for wastewater emissions control is $30,907,772 and the O & M cost for this component is $5,644,605. For all facilities in the Final Pharmaceutical Industry Effluent Guideline analyses, the total MACT standards capital cost is $102,822,547 and O & M is $30,535,434. Table B-2 and B-3 present the MACT standards costs as received by EPA, in 1995 dollars and for all facilities, including some that are not in the Final Pharmaceutical Industry Effluent Guideline analysis.

Table B-2 presents costs associated with air emission controls and Table B-3 presents costs for wastewater emission controls as well as the total costs for the MACT standards rule (the total costs are the sum of costs for air emission controls and wastewater emission controls). Note than an additional $17,441,041 in capital costs and $5,471,834 in O & M costs are estimated to be incurred by pharmaceutical facilities that are not in the Final Pharmaceutical Industry Effluent Guideline analyses.

Two numbering schemes were assigned to facilities for OAQPS MACT standards costs: a facility number and a plant number. The facility numbers were generated by OAQPS based on the number of pharmaceutical facilities which were sent questionnaires. Of the OAQPS facilities, there are 101 major sources covered under the air regulation. These 101 facilities, which correspond to the numbers in the Air Proposal Economic Impact Assessment, were numbered 1 through 99 in the cost data (one facility was found to be a duplicate and an additional three were not assigned costs) and were matched up to the corresponding OW 30000 facility codes using wastewater impacts listed by stream. OW matched the streams by process of elimination based on OAQPS' description of the streams and its costing for plant process vents and storage tanks. However, not all of the plant numbers from OAQPS have OW facility codes because some plants regulated under the MACT rule do not face effluent guidelines regulation. Also, many of the facilities in the Final Pharmaceutical Industry Effluent Guidelines analysis do not face MACT standards regulation. OAQPS

Table B-1

Capital and O&M Costs for MACT Standards Rule
Final Pharmaceutical Industry Effluent Guideline Facilities Only
(1990 Dollars)*

Plant Number	Facility ID	Total Wastewater Costs		Total Costs	
		Capital	O & M	Capital	O & M
4	30122	$0	$0	$19,059	$7,960
7	30547	$0	$0	$568,262	$211,802
8	30278	$0	$0	$745,452	$227,147
9	30759	$5,153,204	$866,990	$5,744,433	$1,133,147
24	30207	$0	$0	$24,681	$8,185
30	30107	$0	$0	$458,929	$170,245
34	30172	$0	$0	$24,681	$11,343
39	30851	$0	$0	$47,649	$53,064
43	30094	$0	$0	$258,679	$69,525
63	30110	$0	$0	$24,681	$8,185
68	30387	$0	$0	$24,681	$8,185
73	31110	$0	$0	$435,962	$150,634
77	30431	$1,040,441	$206,303	$1,327,709	$298,823
79	30977	$408,121	$76,507	$1,291,494	$368,204
80	30954	$1,911,515	$321,365	$2,341,855	$490,725
87	30756	$527,939	$102,126	$1,078,763	$247,728
95	30071	$0	$0	$47,649	$84,649
106	30228	$0	$0	$24,681	$8,185
120	30965	$0	$0	$24,681	$17,660
121	30762	$0	$0	$573,791	$190,481
122	30639	$0	$0	$877,752	$288,314
124	31040	$0	$0	$6,474,787	$2,144,749
126	30331	$370,706	$70,238	$2,069,098	$645,947
135	30258	$0	$0	$47,649	$12,004
141	30504	$0	$0	$53,271	$28,021
145	30125	$0	$0	$19,059	$55,337
160	31123	$0	$0	$430,340	$140,934
168	30701	$0	$0	$311,204	$80,878
169	30329	$0	$0	$6,027,034	$2,270,742
186	30401	$0	$0	$875,831	$293,969
193	30900	$0	$0	$1,106,221	$399,402
196	30022	$0	$0	$1,692,770	$569,167
198	30610	$524,993	$101,320	$2,217,763	$676,804
203	31164	$711,192	$152,220	$6,091,105	$2,069,753
204	31112	$0	$0	$596,851	$212,687
212	30147	$0	$0	$562,640	$211,577
220	30540	$0	$0	$1,660,952	$578,765
221	30010	$6,830,432	$1,149,271	$8,359,084	$1,654,234
222	30767	$0	$0	$4,421,834	$1,545,187
223	30884	$0	$0	$830,849	$289,820
224	30822	$0	$0	$305,582	$80,654
239	31113	$0	$0	$24,681	$8,185
246	31121	$596,753	$120,937	$650,023	$142,641
247	31120	$452,418	$83,255	$1,705,319	$502,771
249	30050	$0	$0	$568,262	$205,485
260	30548	$0	$0	$264,301	$69,750
270	30864	$1,030,113	$173,440	$1,054,794	$181,625
271	30918	$817,967	$181,408	$1,414,819	$397,254
279	30819	$0	$0	$458,929	$173,404
280	30542	$0	$0	$1,385,201	$490,159
310	30690	$0	$0	$1,258,523	$457,642
313	30910	$0	$0	$47,649	$30,955
314	30694	$0	$0	$305,582	$83,812
318	30931	$0	$0	$2,926,611	$980,723
326	30279	$0	$0	$1,088,782	$339,519
331	30299	$0	$0	$19,059	$7,960
332	30618	$0	$0	$24,681	$27,136
333	30487	$0	$0	$1,281,490	$493,046
337	31078	$0	$0	$592,105	$156,506
339	30949	$1,910,594	$387,181	$5,814,388	$1,547,720
343	30398	$0	$0	$1,684,012	$642,031
344	30033	$517,599	$99,300	$570,870	$143,113
350	30366	$757,596	$164,905	$805,244	$176,909
351	30457	$964,546	$190,145	$1,834,755	$480,730
354	31056	$0	$0	$311,204	$80,878
358	30832	$2,231,667	$462,593	$7,625,960	$2,260,110
359	31029	$3,831,112	$672,526	$5,406,667	$1,163,349
379	30905	$0	$0	$19,059	$61,654
381	31092	$316,154	$62,082	$335,213	$70,042
397	31163	$0	$0	$1,385,201	$487,000
398	30117	$0	$0	$1,830,692	$655,828
Total		$30,905,061	$5,644,110	$102,813,530	$30,532,756

* Deflated from 1995 dollars using ENR Construction Cost Index.

Source: Data provided by U.S. EPA, Office of Air Quality Planning and Standards.

Table B-2

MACT Standards Air Emission Control Costs (1995 dollars)

Plant Number	Facility ID	Equipment Leaks		Dedicated Process Vents		Nondedicated Process Vents		Storage Tanks	
		Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M
4	30122	$0	$3,652	$0	$0	$0	$0	$22,036	$5,551
7	30547	$6,500	$11,215	$628,472	$228,113	$0	$0	$22,036	$5,551
8	30278	$0	$7,304	$331,269	$84,046	$475,510	$157,392	$55,090	$13,878
9	30759	$0	$65,732	$628,472	$228,113	$0	$0	$55,090	$13,878
24	30207	$6,500	$3,912	$0	$0	$0	$0	$22,036	$5,551
30	30107	$0	$25,562	$0	$0	$475,510	$157,392	$55,090	$13,878
34	30172	$6,500	$7,564	$0	$0	$0	$0	$22,036	$5,551
39	30851	$0	$47,473	$0	$0	$0	$0	$55,090	$13,878
43	30094	$0	$3,652	$277,041	$71,180	$0	$0	$22,036	$5,551
63	30110	$6,500	$3,912	$0	$0	$0	$0	$22,036	$5,551
68	30387	$6,500	$3,912	$0	$0	$0	$0	$22,036	$5,551
73	31110	$6,500	$11,215	$0	$0	$475,510	$157,392	$22,036	$5,551
77	30431	$0	$21,911	$277,041	$71,180	$0	$0	$55,090	$13,878
79	30977	$6,500	$11,215	$959,741	$312,159	$0	$0	$55,090	$13,878
80	30954	$0	$32,866	$0	$0	$475,510	$157,392	$22,036	$5,551
87	30756	$6,500	$7,564	$608,310	$155,226	$0	$0	$22,036	$5,551
95	30071	$0	$83,990	$0	$0	$0	$0	$55,090	$13,878
106	30228	$6,500	$3,912	$0	$0	$0	$0	$22,036	$5,551
120	30965	$6,500	$14,867	$0	$0	$0	$0	$22,036	$5,551
121	30762	$0	$51,125	$608,310	$155,226	$0	$0	$55,090	$13,878
122	30639	$0	$7,304	$959,741	$312,159	$0	$0	$55,090	$13,878
124	31040	$0	$29,214	$331,269	$84,046	$7,132,655	$2,360,884	$22,036	$5,551
126	30331	$6,500	$22,171	$0	$0	$1,902,041	$629,569	$55,090	$13,878
135	30258	$0	$0	$0	$0	$0	$0	$55,090	$13,878
141	30504	$6,500	$18,519	$0	$0	$0	$0	$55,090	$13,878
145	30125	$0	$58,428	$0	$0	$0	$0	$22,036	$5,551
160	31123	$0	$0	$0	$0	$475,510	$157,392	$22,036	$5,551
168	30701	$6,500	$3,912	$331,269	$84,046	$0	$0	$22,036	$5,551
169	30329	$0	$102,249	$6,913,191	$2,509,239	$0	$0	$55,090	$13,878
186	30401	$6,500	$11,215	$0	$0	$951,021	$314,785	$55,090	$13,878
193	30900	$0	$0	$1,256,944	$456,225	$0	$0	$22,036	$5,551
196	30022	$0	$14,607	$0	$0	$1,902,041	$629,569	$55,090	$13,878
198	30610	$0	$21,911	$0	$0	$1,902,041	$629,569	$55,090	$13,878
203	31164	$0	$102,249	$1,885,416	$684,338	$4,279,593	$1,416,531	$55,090	$13,878
204	31112	$6,500	$3,912	$628,472	$228,113	$0	$0	$55,090	$13,878
212	30147	$0	$10,955	$628,472	$228,113	$0	$0	$22,036	$5,551

Table B-2 (continued)

Plant Number	Facility ID	Equipment Leaks		Dedicated Process Vents		Nondedicated Process Vents		Storage Tanks	
		Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M
220	30540	$0	$43,821	$1,865,254	$611,451	$0	$0	$55,090	$13,878
221	30010	$0	$29,214	$1,236,782	$383,339	$475,510	$157,392	$55,090	$13,878
222	30767	$0	$105,901	$4,581,794	$1,509,329	$475,510	$157,392	$55,090	$13,878
223	30884	$0	$21,911	$905,513	$299,293	$0	$0	$55,090	$13,878
224	30822	$0	$3,652	$331,269	$84,046	$0	$0	$22,036	$5,551
239	31113	$6,500	$3,912	$0	$0	$0	$0	$22,036	$5,551
246	31121	$6,500	$11,215	$0	$0	$0	$0	$55,090	$13,878
247	31120	$0	$7,304	$0	$0	$1,426,531	$472,177	$22,036	$5,551
249	30050	$6,500	$3,912	$628,472	$228,113	$0	$0	$22,036	$5,551
260	30548	$6,500	$3,912	$277,041	$71,180	$0	$0	$22,036	$5,551
270	30864	$6,500	$3,912	$0	$0	$0	$0	$22,036	$5,551
271	30918	$6,500	$7,564	$628,472	$228,113	$0	$0	$55,090	$13,878
279	30819	$0	$29,214	$0	$0	$475,510	$157,392	$55,090	$13,878
280	30542	$0	$18,259	$628,472	$228,113	$951,021	$314,785	$22,036	$5,551
310	30690	$6,500	$51,385	$0	$0	$1,426,531	$472,177	$22,036	$5,551
313	30910	$0	$21,911	$0	$0	$0	$0	$55,090	$13,878
314	30694	$0	$7,304	$331,269	$84,046	$0	$0	$22,036	$5,551
318	30931	$0	$18,259	$0	$0	$3,328,572	$1,101,746	$55,090	$13,878
326	30279	$0	$3,652	$1,236,782	$383,339	$0	$0	$22,036	$5,551
331	30299	$0	$3,652	$0	$0	$0	$0	$22,036	$5,551
332	30618	$6,500	$25,822	$0	$0	$0	$0	$22,036	$5,551
333	30487	$0	$83,990	$0	$0	$1,426,531	$472,177	$55,090	$13,878
337	31078	$0	$7,304	$662,538	$168,093	$0	$0	$22,036	$5,551
339	30949	$0	$47,473	$3,507,342	$965,645	$951,021	$314,785	$55,090	$13,878
343	30398	$6,500	$44,081	$1,885,416	$684,338	$0	$0	$55,090	$13,878
344	30033	$6,500	$36,778	$0	$0	$0	$0	$55,090	$13,878
350	30366	$0	$0	$0	$0	$0	$0	$55,090	$13,878
351	30457	$0	$7,304	$0	$0	$951,021	$314,785	$55,090	$13,878
354	31056	$6,500	$3,912	$331,269	$84,046	$0	$0	$22,036	$5,551
358	30832	$0	$18,259	$0	$0	$6,181,634	$2,046,100	$55,090	$13,878
359	31029	$0	$0	$1,291,010	$396,205	$475,510	$157,392	$55,090	$13,878
379	30905	$0	$65,732	$0	$0	$0	$0	$22,036	$5,551
381	31092	$0	$3,652	$0	$0	$0	$0	$22,036	$5,551
397	31163	$0	$14,607	$628,472	$228,113	$951,021	$314,785	$22,036	$5,551
398	30117	$6,500	$44,081	$628,472	$228,113	$1,426,531	$472,177	$55,090	$13,878

Table B-3

MACT Standards Wastewater Emission Control and Total MACT Standards Costs (1995 dollars)

Plant Number	Facility ID	Partially Soluble Wastewater		Soluble Wastewater		Total Wastewater		Total Costs	
		Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M
4	30122	$0	$0	$0	$0	$0	$0	$22,036	$9,203
7	30547	$0	$0	$0	$0	$0	$0	$657,008	$244,879
8	30278	$0	$0	$0	$0	$0	$0	$861,869	$262,620
9	30759	$5,957,984	$1,002,389	$0	$0	$5,957,984	$1,002,389	$6,641,546	$1,310,111
24	30207	$0	$0	$0	$0	$0	$0	$28,536	$9,463
30	30107	$0	$0	$0	$0	$0	$0	$530,600	$196,833
34	30172	$0	$0	$0	$0	$0	$0	$28,536	$13,115
39	30851	$0	$0	$0	$0	$0	$0	$55,090	$61,351
43	30094	$0	$0	$0	$0	$0	$0	$299,077	$80,383
63	30110	$0	$0	$0	$0	$0	$0	$28,536	$9,463
68	30387	$0	$0	$0	$0	$0	$0	$28,536	$9,463
73	31110	$0	$0	$0	$0	$0	$0	$504,046	$174,159
77	30431	$477,956	$89,124	$724,971	$149,397	$1,202,927	$238,521	$1,535,058	$345,490
79	30977	$471,857	$88,455	$0	$0	$471,857	$88,455	$1,493,188	$425,707
80	30954	$2,210,038	$371,552	$0	$0	$2,210,038	$371,552	$2,707,584	$567,362
87	30756	$0	$0	$610,388	$118,075	$610,388	$118,075	$1,247,234	$286,416
95	30071	$0	$0	$0	$0	$0	$0	$55,090	$97,868
106	30228	$0	$0	$0	$0	$0	$0	$28,536	$9,463
120	30965	$0	$0	$0	$0	$0	$0	$28,536	$20,418
121	30762	$0	$0	$0	$0	$0	$0	$663,400	$220,229
122	30639	$0	$0	$0	$0	$0	$0	$1,014,831	$333,341
124	31040	$0	$0	$0	$0	$0	$0	$7,485,960	$2,479,696
126	30331	$428,599	$81,207	$0	$0	$428,599	$81,207	$2,392,230	$746,825
135	30258	$0	$0	$0	$0	$0	$0	$55,090	$13,878
141	30504	$0	$0	$0	$0	$0	$0	$61,590	$32,397
145	30125	$0	$0	$0	$0	$0	$0	$22,036	$63,979
160	31123	$0	$0	$0	$0	$0	$0	$497,546	$162,944
168	30701	$0	$0	$0	$0	$0	$0	$359,805	$93,509
169	30329	$0	$0	$0	$0	$0	$0	$6,968,281	$2,625,366
186	30401	$0	$0	$0	$0	$0	$0	$1,012,611	$339,878
193	30900	$0	$0	$0	$0	$0	$0	$1,278,980	$461,777
196	30022	$0	$0	$0	$0	$0	$0	$1,957,131	$658,054
198	30610	$0	$0	$606,981	$117,143	$606,981	$117,143	$2,564,112	$782,501
203	31164	$0	$0	$822,259	$175,992	$822,259	$175,992	$7,042,358	$2,392,988
204	31112	$0	$0	$0	$0	$0	$0	$690,062	$245,903
212	30147	$0	$0	$0	$0	$0	$0	$650,508	$244,619

Table B-3 (continued)

Plant Number	Facility ID	Partially Soluble Wastewater		Soluble Wastewater		Total Wastewater		Total Costs	
		Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M	Total Capital	Annual O&M
220	30540	$0	$0	$0	$0	$0	$0	$1,920,344	$669,151
221	30010	$7,897,146	$1,328,753	$0	$0	$7,897,146	$1,328,753	$9,664,529	$1,912,577
222	30767	$0	$0	$0	$0	$0	$0	$5,112,395	$1,786,500
223	30884	$0	$0	$0	$0	$0	$0	$960,603	$335,081
224	30822	$0	$0	$0	$0	$0	$0	$353,305	$93,249
239	31113	$0	$0	$0	$0	$0	$0	$28,536	$9,463
246	31121	$0	$0	$689,948	$139,823	$689,948	$139,823	$751,538	$164,917
247	31120	$523,073	$96,257	$0	$0	$523,073	$96,257	$1,971,640	$581,289
249	30050	$0	$0	$0	$0	$0	$0	$657,008	$237,576
260	30548	$0	$0	$0	$0	$0	$0	$305,577	$80,643
270	30864	$1,190,986	$200,526	$0	$0	$1,190,986	$200,526	$1,219,522	$209,989
271	30918	$0	$0	$945,710	$209,739	$945,710	$209,739	$1,635,772	$459,293
279	30819	$0	$0	$0	$0	$0	$0	$530,600	$200,485
280	30542	$0	$0	$0	$0	$0	$0	$1,601,529	$566,707
310	30690	$0	$0	$0	$0	$0	$0	$1,455,067	$529,113
313	30910	$0	$0	$0	$0	$0	$0	$55,090	$35,789
314	30694	$0	$0	$0	$0	$0	$0	$353,305	$96,901
318	30931	$0	$0	$0	$0	$0	$0	$3,383,662	$1,133,883
326	30279	$0	$0	$0	$0	$0	$0	$1,258,818	$392,542
331	30299	$0	$0	$0	$0	$0	$0	$22,036	$9,203
332	30618	$0	$0	$0	$0	$0	$0	$28,536	$31,374
333	30487	$0	$0	$0	$0	$0	$0	$1,481,621	$570,045
337	31078	$0	$0	$0	$0	$0	$0	$684,574	$180,947
339	30949	$1,038,184	$176,382	$1,170,789	$271,266	$2,208,973	$447,648	$6,722,425	$1,789,428
343	30398	$0	$0	$0	$0	$0	$0	$1,947,006	$742,297
344	30033	$0	$0	$598,433	$114,807	$598,433	$114,807	$660,023	$165,463
350	30366	$0	$0	$875,910	$190,658	$875,910	$190,658	$931,000	$204,536
351	30457	$433,448	$82,262	$681,732	$137,578	$1,115,180	$219,840	$2,121,291	$555,806
354	31056	$0	$0	$0	$0	$0	$0	$359,805	$93,509
358	30832	$1,163,395	$196,322	$1,416,793	$338,514	$2,580,188	$534,836	$8,816,912	$2,613,073
359	31029	$3,658,071	$615,479	$771,349	$162,075	$4,429,420	$777,555	$6,251,030	$1,345,031
379	30905	$0	$0	$0	$0	$0	$0	$22,036	$71,283
381	31092	$365,528	$71,777	$0	$0	$365,528	$71,777	$387,564	$80,980
397	31163	$0	$0	$0	$0	$0	$0	$1,601,529	$563,055
398	30117	$0	$0	$0	$0	$0	$0	$2,116,593	$758,249

has provided OW with costs for 98 facilities, 71 of which overlap with OW regulations. The ultimate mapping of facility numbers (from OAQPS numbers to OW numbers) was generated by OAQPS, in conjunction with OW.